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Stark Phase III: Is The Third Time The Charm?

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On August 27, 2007, the Centers for Medicare and Medicaid Services (CMS) released a display copy of the Phase III final regulations to the Stark Law (Phase III). Phase III comes just two months after CMS proposed other, perhaps more sweeping, Stark Law regulatory changes and only days before CMS is expected to launch a national Stark Law compliance initiative by sending detailed, mandatory financial relationship questionnaires to 500 hospitals.

The attached [chart](#) provides a brief overview of the Phase III final regulations and the potential additional Stark Law regulatory changes that CMS proposed as part of its 2008 Medicare Physician Fee Schedule Proposed Rule (MPFS Proposed Rule)[1]. As the [chart](#) demonstrates and as discussed below, Phase III offers needed flexibility to hospitals and physicians seeking to comply with the Stark Law. However, the MPFS Proposed Rule and Phase III's broad "stand in the shoes" rule for indirect compensation arrangements temper this flexibility by targeting several common hospital-physician relationships for dramatic change or elimination. The cumulative effect of these pending and proposed regulatory changes, together with the national Stark Law compliance initiative, creates an enforcement environment that targets perceived abuse and may require hospitals to self-report such abuse.

Effective Date

Phase III becomes effective 90 days after publication in the *Federal Register*, which occurred on September 5, 2007 (72 Fed. Reg. 51012). Phase III does not generally grandfather pre-existing arrangements, but, as discussed below, offers limited protection against the application of the new "stand in the shoes" rule for indirect compensation arrangements.

Effect on Medicare Payment Rules

Phase III expressly states what the Stark Law regulations previously only implied with respect to their effect on Medicare billing rules. That is, the Stark Law regulations do not alter any obligations under the reassignment rule, the purchased diagnostic test rule, the requirements for "incident to" services and supplies, or any other applicable Medicare laws, rules, or regulations. *See* 42 C.F.R. § 411.350(d). This new provision was intended to clarify that the Stark Law regulations do not override other Medicare payment principles.

Group Practices

Physicians in the Group Practice. Phase III revises the definition of "physician in the group practice" to require a direct contractual relationship between the physician and the group practice. This new requirement may preclude groups from including physicians who provide services to group practices

under a professional services agreement between the group practice and the independent contractor physician's group practice entity (though *locum tenens* physicians are included, without specifying contract or employment relationships, in the definition of "members of the group"). Notwithstanding the recent change to the reassignment provisions of Section 1842(b)(6) of the Social Security Act (the Act) to permit independent contractor physicians to reassign their claims to a group practice for services performed off-premises, CMS emphasized that independent contractors are considered members of the group practice *only* when providing services in the group practice's facilities. CMS stated that these requirements ensure that independent contractor physicians maintain a "clear and meaningful nexus with the group's medical practice." In addition, it is CMS' view that employees leased from other entities do not possess such a nexus and that "this justifies excluding a leased employee from being a 'physician in the group practice,' . . ."

Profit Sharing and Productivity Bonuses. Under existing (pre-Phase III) regulations, group practices are permitted to pay a "physician in the group practice" either a share of the overall profits or a productivity bonus that is based on personally performed services (including services provided "incident to" those personally performed services) as long as the profit sharing or bonus is not determined in any manner that is "directly related" to the referring physician's volume or value of DHS referrals. In the preamble to the Phase II rule, CMS based this position on an interpretation of the statutory language, noting that:

Section 1877(h)(4)(B)(i) of the Act expressly permits a physician in the group practice to receive a profit share or productivity bonus based directly on services that he or she personally performs and services that are "incident to" his or her personally performed services. We have revised the regulations to make clear that profit shares or productivity bonuses can be based directly on services that are "incident to" the physician's personally performed services.

The Phase III regulations regarding productivity bonuses and profit shares, when read in conjunction with CMS' preamble to Phase III, make it clear that *overall profit shares* in a group practice may no longer be based on the volume or value of "incident to" services referred by the physicians. CMS' rationale is that its earlier interpretation (allowing such a division) was inconsistent with the clear statutory language that references "incident to" services only in connection with productivity bonuses. CMS noted, however, that the overall profits would, by definition, include profits from "incident to" services, and as such may be paid out, on an indirect basis, as a share of the overall profits of the group from DHS.

With respect to productivity bonuses, Phase III more clearly incorporates the specific language promised in Phase I and Phase II that makes it clear that productivity bonuses may be *directly* related to the volume or value of either services personally performed by the referring physician, his or her referrals for services that are "incident to" those personally performed services, or both. In determining such productivity bonuses, any incident to services are to be attributed to the ordering physician (not the supervising physician, if the supervising physician is a different person than the ordering physician) and, as is discussed in the following paragraph, diagnostic tests are not considered to be "incident to" services. Separately, with respect to those services that may be personally performed by a physician, it should be noted that, in its discussion of the definition of a Stark Law "referral," CMS observes that "[t]here are few, if any, situations in which a referring physician would personally furnish [durable medical equipment (DME)] and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in § 424.57(c)." So while permitting the direct attribution of personally performed services and incident to services in calculating productivity bonuses is helpful, the restriction on the scope of those services has substantially negated that benefit.

Definition of “Incident to” Services. Since 2001 through the release of Phase III, substantial ambiguity and conflicting advice from CMS surrounded what types of services and supplies may be furnished on an “incident to” basis. Phase III clarifies this ambiguity by stating clearly that “incident to” services and supplies excludes services or supplies, such as x-rays or diagnostic imaging procedures, that have a separate Medicare benefit category except as otherwise expressly permitted by statute (for example, certain physical therapy services and outpatient prescription drugs). The unambiguous articulation of this principle in Phase III will likely create some concern within the physician community because group practices will now clearly be precluded from directly attributing the group practice’s income from diagnostic tests that have historically been billed on an “incident to” basis (notwithstanding their separate benefit category) to the ordering (“incident to”) physician for purposes of calculating personal productivity bonuses. Rather, those compensation models will need to be restructured so that the income from these services is distributed, on an indirect basis, as a share of the overall profits of the group from the performance of DHS.

Centralized Decision Making; Physician Control. In the discussion of “group practices” in the Phase III preamble, CMS addressed comments regarding Internal Revenue Service (IRS) rules that require a majority community board if the group practice seeks exemption as a Section 501(c)(3) organization. The extent of physician control is often a contentious negotiating point between charitable hospitals and affiliated physician groups. CMS responded to these concerns by stating that the Stark Law regulations do not require a majority physician board, and that an organization having a majority community board may qualify as a group practice. CMS did suggest gratuitously that a majority physician board “might be a reasonable and prudent way to ensure fair representation” and to satisfy the centralized decision making requirement of 42 C.F.R. § 411.352(f)(1)(i). The IRS likely would require some special circumstances to approve exemption for such a physician-controlled entity.^[2] Moreover, even if the group practice is taxable, if it is established and funded by the hospital, physician control may increase the possibility that private inurement will occur without appropriate controls reserved to the tax-exempt hospital.

Hospital Ownership. CMS again confirmed in the Phase III preamble that separate legal entities formed by hospitals can qualify as Stark Law group practices. CMS cautioned, however, that if the entity includes multiple specialties in divisions that are separately incorporated the entity may not qualify as a group practice. The preamble did not address CMS’ prior position that hospital entities themselves cannot be group practices (because they are not operated primarily for the purpose of being a physician group practice).

Medical Foundations. In Phase III, CMS once again refused to make a blanket determination that all medical foundations qualify as group practices. However, “[i]n States in which a foundation (or other corporation) may provide physician services, a medical foundation may be a group practice if all of the group practice requirements are satisfied.” CMS further notes that “[w]ith the new ‘stand in the shoes’ provision . . . , many arrangements involving foundation-model structures may be deemed to be direct compensation arrangements and potentially qualify for the personal service arrangements exception.”

Indirect Compensation Arrangements

The Stark regulations distinguish between direct and indirect compensation arrangements, with different sets of exceptions available for each. In Phase II, CMS adopted a limited “stand in the shoes” rule, redefining the term “referring physician” to treat a physician as standing in the shoes of his or her wholly owned professional corporation (PC). 42 C.F.R. § 411.351; 69 Fed. Reg. at 16060. Accordingly, any contract between a sole physician PC and a DHS entity would be a direct compensation arrangement under the Phase II rule.

In Phase III, CMS added a definition of “direct compensation arrangement” and adopted a “stand in the shoes” rule for analyzing indirect compensation arrangements. A direct compensation arrangement will exist for Stark Law purposes if remuneration (anything of value) passes directly between a DHS entity and the physician or his or her immediate family member without going through any intervening person or entity, or if the only intervening entity is a “physician organization.”

The term “physician organization” is defined as a physician, a PC with a single physician as the sole owner, a physician practice, or a group practice. The literal wording of the regulation does not include corporations, partnerships, or limited liability companies unless they are a “physician practice or a group practice.” Accordingly, physicians wishing to enter service or leasing arrangements with hospitals may want to consider using a separate business corporation, LLC or partnership to conduct such business or hold the asset being leased to the hospital and rely on the indirect compensation arrangement framework to protect the relationship under the Stark Law regulations. CMS, however, was sharply critical of physician ownership of leasing and staffing companies in the Phase III preamble (“These arrangements appear highly suspect under the anti-kickback statute; . . .”), noting that it is studying the issue and intends to monitor the Stark Law compliance of such arrangements.

As noted above, CMS will apply the stand in the shoes rule to the physician side of indirect compensation arrangements by collapsing the financial relationships when the DHS entity contracts with a “physician organization.” All such arrangements must meet a direct compensation arrangement exception, with the physician deemed to “stand in the shoes” of the physician organization and to have the same financial relationships with the same DHS entities as the physician organization and all of its members, employees, and independent contractors. 42 C.F.R. § 411.354(c)(3). With respect to those Stark Law exceptions that incorporate the volume or value standard, this means that the physician organization will need to ensure that the proposed compensation arrangement does not include the volume or value of referrals or other business generated between (i.e., by or for) any of those parties *vis a vis* the DHS entity. The resulting analysis could be quite complex, particularly for multi-physician group practices where other physicians in the practice may have a variety of separate agreements (medical director, call coverage, etc.) that need to be analyzed. Presumably, physician organizations will need to cross-reference or maintain a separate master list of all other agreements between their physicians and each DHS entity with whom they contract.

As noted above, Phase III generally is effective 90 days after publication in the *Federal Register*; however, existing indirect compensation arrangements in place before publication of the rule (Sept. 5, 2007) will be grandfathered for the initial or current renewal term (so the extent of the problems caused by the changes to the indirect compensation framework will depend on the length of remaining term). Providers, however, will have the option of applying the stand in the shoes rule to current contracts before they expire. CMS kept the indirect compensation arrangement exception for other circumstances. The exception will continue to have application where the contracting party is not a physician organization, including specifically a chain that runs from DHS entity to management company to referring physician (a very positive development for co-management companies that are being established to manage hospital services lines).

The elimination of the indirect compensation arrangement exception for physicians contracting with a DHS entity through their practice is arguably a far more understandable approach than the one CMS dictated in the Phase I rule with the addition of the indirect compensation arrangement definition and corresponding exception. In fact, the industry itself asked CMS repeatedly to collapse the links for the various compensation exceptions, but six years of settled law and careful planning have intervened since those suggestions were made. As a result, the limitation on the application of the indirect compensation framework in Phase III will require a comprehensive examination of all contracts with a

physician organization that were structured based on the indirect compensation exception and that are scheduled to automatically renew for an additional term to make sure that the arrangement is permissible under a different Stark Law exception.

Academic Medical Centers (AMC) Exception

Phase III made some clarifying changes to the physician compensation standard for the AMC exception without changing the substance of that requirement. As clarified, compensation to the referring physician must meet three requirements: (a) total compensation paid by each AMC component (e.g., teaching hospital, medical school, practice plan, foundation) must be set in advance (i.e., aggregate amount, per unit of service or time based fee, or a specific formula for calculating compensation is specified in advance); (b) in the aggregate, compensation paid by all components of the AMC to the referring physician does not exceed fair market value for the services provided by the referring physician; and (c) total compensation paid by each AMC component cannot be determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician for any component of the AMC.

CMS also clarified that the written documentation supporting the existence of the requisite relationship among the AMC components may be contained in one or more written agreements or other written documents adopted by the governing body of each AMC component. This clarification should be helpful for many AMCs whose interrelationships have evolved over the years in a patchwork of letter agreements and other written documents. Although a single master affiliation agreement may be the preferred option for avoiding confusion and ensuring that the documentation is complete, that approach is not mandatory for qualifying as an AMC.

Finally, CMS imposed a new limitation on the ability of AMCs to count volunteer and courtesy faculty in determining whether the majority of medical staff physicians are faculty physicians.^[3] Phase III continues to provide that the AMC “may” count any faculty member in the majority medical staff test, including volunteer and courtesy faculty, in the numerator (the number of faculty physicians). AMCs, however, also must count all physicians holding the same class of staff privileges in the denominator (the size of the total medical staff). For example, if volunteer faculty have limited courtesy staff privileges at the hospital, the hospital also must count all non-faculty courtesy staff in the denominator. In light of this change, AMCs may wish to review and take action to reduce the size of non-faculty courtesy staff and other secondary staff categories that do not entail full admitting privileges.

Changes in the definition of indirect compensation arrangements may be of more concern to AMCs than the changes to the AMC exception. Any AMC relying on the indirect compensation arrangements definition or exception without verifying compliance with the Stark Law AMC exception may be at risk and should strongly consider initiating a compliance review of its existing faculty and medical school relationships to verify that all components and all support fit within the scope of permitted arrangements within the AMC exception or that those financial relationships that are outside the protection of the AMC exception are within the terms of another Stark Law exception (e.g., physician recruitment and personal services arrangements). Many academic medical centers have relied on the indirect compensation arrangement exception and taken the position that they do not need to determine compliance with the AMC exception. Other AMCs were more proactive in this area and have already been working diligently to meet the AMC exception. Those that have not done so already may have some serious catching up to do in evaluating their contracts to either find a direct compensation arrangement that fits or to get comfortable that they qualify for the AMC exception. Although the regulations are generally effective in 90 days, hospitals and AMCs with existing contracts will have the benefit of a limited grandfathering period until the end of the current term of the contract, assuming the

contract is in force on September 5, 2007.

In-Office Ancillary Services Exception

Despite concerns expressed by CMS in the preamble to the MPFS Proposed Rule about the burgeoning scope of the in-office ancillary services exception, Phase III does not make any significant changes to this exception. CMS did, however, emphasize in the preamble to Phase III that a part-time arrangement cannot meet the centralized building location option for the in-office ancillary services exception. Additionally, CMS expressed skepticism that shared use of space or equipment in the same building could satisfy the exception. CMS stated:

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 per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute.

Moreover, CMS noted in the preamble that it may propose further changes to the in-office ancillary services exception to correct what it believes to be abusive arrangements. Specifically, CMS stated:

The in-office ancillary services exception allows a physician to provide DHS to his or her own patients, which may appear to undercut the purpose of the physician self-referral prohibition. Nevertheless, the statutory exception evidences intent by the Congress to permit a physician to furnish DHS to his or her own patients if certain conditions are met. 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.

It remains to be seen what changes, if any, will be included in the final MPFS rule or another rulemaking.

Intra-family Referrals

In apparent recognition of the differing levels of accessibility and travel times in isolated areas, CMS modified the patient travel criterion for the intra-family referral exception. Phase II required that there be no other person or entity (other than the referring physician's family member) available to provide the DHS within 25 miles. Phase III clarifies that the meaning of "availability" must take into account the patient's condition, and that the distance is not the only factor, rather the referring physician also need not look for alternatives that are more than a 45 minute "transportation time" away from the patient's residence. It is not completely clear from the regulations how the time element will be determined and whether actual road conditions are a factor, though the preamble indicates that the determination should be made on the basis of distance, posted speeds and weather conditions (with a suggestion that physicians maintain documentation of these calculations). The use of "transportation time" also introduces some ambiguity. Read literally it could include not only driving but also air travel, subway, train, boat, and even walking depending on the patient's condition and perhaps available modes of transportation. The preamble, however, suggests that driving time is the appropriate measure and suggests documenting the determination of transportation time with printouts of mileage

and driving time (e.g., from Map Quest or Map Blast) and weather conditions.

Ownership and Investment Interests

CMS has reconsidered its position on secured installment sales of equipment and added a specific provision in the regulations stating that a security interest held by a physician in equipment that the physician sold to a hospital and financed through a loan from the physician (e.g., an installment payment arrangement) would be treated as a compensation arrangement and not an ownership or investment interest. *See* 42 C.F.R. § 411.354(b)(3)(v). The exception does not specifically apply to family members or sales to other DHS entities.

Although this exception likely will be viewed as a positive development by many, the added gloss CMS put on this change in the Phase III preamble may cause heightened compliance concerns for hospitals that have issued certain types of participating bonds. In the Phase III preamble, CMS reiterated its view, first expressed in the preamble to the Phase II rule, that other loans (made by a physician) or bonds (purchased by a physician) secured by a particular piece of equipment or the revenue of a hospital department or other discrete hospital operation would be an ownership or investment interest (not a compensation arrangement) and would relate to only a portion of the hospital, making the whole hospital exception unavailable. As a result, it may be more difficult if not impossible to persuade CMS that another Stark Law exception would protect a participating bond transaction where the property ostensibly financed is a piece of equipment or a non-hospital facility, or where interest rates are determined in reference to the performance of, or secured by, discrete portions of hospital revenues (e.g., a particular department). CMS also refused to create a special exception for bonds that are not participatory, noting that investment based on debt, such as bonds, is clearly contemplated in the Stark Law itself to be an ownership or investment interest, regardless of whether the issuer is taxable or tax-exempt.

The Phase III preamble also clarifies that a guaranty of a loan does not create an ownership or investment interest in the debtor; however, it typically would create a compensation arrangement that would need to fit within a compensation arrangement exception.

Lease Exceptions

Phase II added a provision allowing a holdover for leases of office space or equipment for up to six months on the same terms as the expired lease. In the preamble to Phase III CMS agreed that landlords can charge a premium rental for the holdover, but it declined to extend the maximum holdover period beyond six months, even where the landlord is taking steps to evict the tenant.

There appears to be no change yet for “per click” leases under Stark, and that subject likely will be handled in the final MPFS rule. As noted above, however, CMS strongly suggests that, even without additional regulations prohibiting “per click” leases, such arrangements may not satisfy all requirements of the lease exception, particularly supervision requirements.

The Phase III preamble also advised that parties may not amend lease agreements to change rental charges. Rather, parties would need to terminate the existing agreement and enter into a new agreement that meets the requirements of the applicable Stark Law exception. If the agreement is in the first year of its original term, the parties may not enter into a new agreement until after the end of the first year of the original lease term. CMS did not provide its reasoning as to why a new agreement is substantively preferable to an amended agreement.

Bona Fide Employment Exception

The employment exception in Phase III is most notable for what did not change. Although CMS clarified that group practices may pay productivity bonuses based directly on the volume or value of services performed incident to the professional medical services of the referring (ordering) physician, there is no corresponding change in the employment exception. Although there is a popular misconception among physicians and some counsel that Stark includes a “group practice exception,” that is incorrect. The group practice provisions are definitional. If a group qualifies as a group practice, it has added flexibility for referrals under certain other exceptions such as the physician services and in-office ancillary services exceptions. As a result, group practices will be able to take advantage of the additional flexibility for payments based on “incident to” services only for services that fit within the in-office ancillary services exception (and not payments for other services for which the group must rely on the employment exception). Also, physicians employed by entities that do not qualify as group practices (e.g., medical group operated as an unincorporated division of a hospital) will not be eligible for productivity bonuses based on the volume or value of “incident to” services or supplies that they order or supervise.

In the past, a number of hospitals also have considered relying on the in-office ancillary services exception for their employed physicians outside of a group practice setting. In the Phase III preamble, CMS questions that approach, indicating that where the hospital bills for the referred DHS (presumably under the hospital’s provider number), the hospital and not the physician would be furnishing the DHS and the in-office ancillary services exception would not apply. CMS declined to expand the in-office ancillary services or employee exceptions to address this area.

Personal Service Arrangements Exception

Phase III adds a provision (similar to that found in the leasing exceptions) allowing a holdover under a professional service agreement for up to six months on the same terms as the expired contract following at least a one-year term. As with lease agreements, CMS indicated that personal services agreements should not be amended to change compensation paid to physicians. Instead, the existing agreement should be terminated and a new agreement with the revised compensation terms should be entered into by the parties.

Fair Market Value

Phase III deletes the safe harbor that CMS had established for hourly payments to physicians for personal services. *See* 42 C.F.R. § 411.351. Previously, the Stark Law regulations allowed physicians and hospitals to guarantee that hourly payments did not exceed fair market value by setting the payment at a rate less than or equal to the rate for emergency room physicians in the “relevant physician market” (minimum of three hospitals) or the average of the 50th percentile of national compensation levels for physicians in the same specialty in at least four of six specific surveys.

In the commentary, CMS noted that the payment rates hospitals and physicians would need to analyze in order to take advantage of the safe harbor were difficult, if not impossible to obtain. CMS stated:

We are aware that several of the surveys are no longer available (or may not be readily available to all DHS entities and physicians), making it impractical to utilize the safe harbor. In addition, it may be infeasible to obtain information regarding hourly rates for emergency room physicians at competitor hospitals. . . .

Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value. Ultimately, the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors. As we explained in Phase II, although a good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party's intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself.

The impact of this change is likely minimal—CMS removed a safe harbor that was not very useful, and some might argue it was counterproductive because it set an unreasonably low threshold. At least the elimination of the safe harbor arguably removes any negative inference that an hourly rate above the 50th percentile from the salary surveys exceeds fair market value.

Without the safe harbor, Phase III leaves hospitals and physicians on their own to determine whether a payment rate is consistent with fair market value. As CMS noted in the preamble:

Nothing precludes parties from calculating fair market value using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits the definition at section 1877(h) of the Act and § 411.351. Ultimately, fair market value is determined based on facts and circumstances. The appropriate method will depend on the nature of the transaction, its location, and other factors. . . .

Physician Recruitment Exception

Geographic Service Area. Phase III provides added flexibility for recruiting to all hospitals, including rural hospitals, by loosening the definition of the “geographic area served by the hospital”—a term that limits where a recruited physician must establish his or her practice to qualify for hospital recruitment incentives. Prior rules applied a 75% zip code test as the definition, i.e., the smallest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. CMS has clarified that hospitals in general have the flexibility to decide to include zip codes from which they draw no inpatients, as long as those zip codes are surrounded on all sides by other zip codes that meet the 75% test. CMS also clarified that hospitals with more far-flung service areas that may not be able to configure any list of wholly contiguous zip codes meeting the 75% test can use the area of contiguous zip codes that gets them closest to 75%. Rural hospitals also have the option to increase the percentage to 90%, i.e., the contiguous zip codes from which they draw at least 90% of their inpatients and then, if necessary to hit 90%, adding non-contiguous zip codes starting with those producing the highest percentage of inpatients for the hospital until the 90% level is reached. 42 C.F.R. § 411.357(e)(2).

Relocation Requirement. Another area of confusion under the physician recruitment exception has been the meaning of the relocation requirement and the extent to which it may preclude cross-town recruitment. Phase III clarifies that, other than physicians specifically excepted from the relocation requirement, to take advantage of the physician recruitment exception, the recruited physician must be recruited from a medical practice located outside of the geographic area served by the hospital and must establish a medical practice within the geographic area served by the hospital.^[4] CMS has continued the exceptions to the relocation requirement for physicians in practice one year or less, and added two new exceptions: (a) physicians employed for at least two years on a full-time basis in one of three specific public service settings (i.e., serving a prison population, serving military personnel and their families through the Department of Defense or Veterans Affairs, or at an Indian Health Service facility); or (b) physicians with respect to whom CMS issues an advisory opinion holding that the physician “does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.” 42 C.F.R. § 411.357(e)(3)(iii).

Similarly, hospitals located in a rural area have the flexibility, with an approving advisory opinion that confirms community need, to recruit a physician to an area outside the geographic area served by the hospital. 42 C.F.R. § 411.357(e)(5).

The added exceptions to the relocation requirement undoubtedly will help with some arrangements for recruiting physicians who have worked off student loans through public service activities, and ease their transition into private practice. Although the other new exception to the relocation requirement, for physicians without an established practice, provides the promise of some flexibility similar to determinations made by the IRS in prior physician recruitment rulings for cross-town recruitment, that promise may be illusory. The same could be said for the additional or modified exceptions for rural hospital recruitment and retention activities. To date, the advisory opinion process at CMS for the Stark Law has moved far slower and produced significantly fewer opinions than at the Office of Inspector General (OIG) for the Anti-Kickback Statute. In fairness to CMS, however, the delays likely related in part to a lapse in the statutory mandate for such opinions (later corrected), and the lack of final regulations. With the issuance of Phase III in final form and the likely finalization by the end of this year of the remaining open issues from the MPFS Proposed Rule, we may see some acceleration in the pace of issuing advisory opinions on the Stark Law. It is also possible that CMS will develop a streamlined procedure to allow for quicker determinations on this exception, similar to the more rapid turnaround provided on requests related to the former moratorium on physician ownership of specialty hospitals.

CMS also considered and rejected suggestions that the relocation requirement made it unnecessary to limit the recruitment exception to physicians not already on staff at the hospital, or that the hospitals be allowed to provide recruitment incentives to physicians on staff but without active staff privileges. Rather, CMS noted that the physician recruitment exception clearly does not apply to a hospital's offer or payment of recruitment incentives to any physician already on staff, in any category of privileges (whether or not active). Accordingly, CMS seems likely to challenge any recruiting deal for a physician who was already a member of the medical staff before the written recruitment agreement is signed.

Incremental Costs and Replacing Physicians. The physician recruitment exception, as amended in the Phase II regulations, limited the costs that an existing practice may allocate to recruited physicians to the additional incremental costs attributable to the recruited physician. 42 C.F.R. § 411.357(e)(4). Some legal counsel had argued that the wording of the incremental costs standard was ambiguous and only applied to net income guaranties and not to guaranties that focused on practice revenues. To remove any confusion, CMS clarified in Phase III that the incremental costs standard applies whenever a hospital provides an income guaranty "of any type" to a physician recruited to join an existing practice. In the preamble, CMS elaborated that in applying the incremental cost standard, it makes no difference whether the guaranty is one for gross income, net income, revenues or another variation as long as it "involves a potential cost to the guarantor hospital and a benefit to the recipient physician."

CMS has now partially addressed the problem of recruiting replacement physicians for an existing practice by providing some limited relief to the incremental costs standard. Phase III would allow physician practices located in a rural area or health professional shortage area (HPSA) to reallocate some existing overhead as part of a recruitment arrangement to replace a physician who within the prior 12 months either retired, relocated out of the geographic area served by the hospital, or died. The practice could choose to allocate either just the incremental additional expenses, or allocate overall costs (including existing indirect costs) up to the lower of a per capita share of aggregate costs or 20% of the practice's aggregate costs. Although this revision will provide needed assistance for many practices in rural and underserved areas, smaller practices (fewer than 5 physicians) still will have

some financial risk from adding a replacement physician (though they may be able to recover a portion of their ongoing fixed overhead costs). The revision also does nothing to assist practices in other non-rural, non-HPSA areas needing to replace a retiring, relocating, or deceased physician. *See* 42 C.F.R. § 411.357(e)(4).

Reasonable Practice Restrictions. For physicians recruited into an existing practice, Phase III also would provide some flexibility for protecting the practice's interests by loosening somewhat the prohibition on practice restrictions to clearly allow more than pure quality measures. The regulations would now only prohibit practice restrictions that "unreasonably restrict" the recruit's ability to practice in the geographic area served by the hospital. 42 C.F.R. § 411.357(e)(4)(vi). CMS explained in the preamble that it only intended in Phase II to prohibit practice restrictions imposed by the practice "that would have a substantial effect on the recruited physician's ability to remain and practice medicine in the hospital's geographic service area after leaving the physician group or group practice." (Emphasis in original.) The preamble also indicates that CMS believes the following practice restrictions may be imposed by the practice and are not unreasonable in that they do not have a substantial effect on the physician's ability to remain in practice in the community:

- No moonlighting
- No solicitation of patients or employees
- Mandatory acceptance of Medicaid and indigent patients
- Prohibit use by the recruit of confidential or proprietary information of the practice
- Require the recruit to repay practice losses in excess of the amount covered by hospital recruitment payments (e.g., losses not covered by an income guaranty)
- Require the recruit to pay a predetermined, "reasonable" amount of liquidated damages if he/she leaves the practice but remains in the community (but not a liquidated damages clause that requires a "significant or unreasonable payment" by the recruited physician)
- Impose "a limited, reasonable non-compete clause" on recruited physicians (though the regulations do not preclude hospitals from prohibiting practices from imposing noncompetes on physician recruits).

In particular, these last two bulleted provisions provide no real guidance as to what is permitted under the exception and may constitute the proverbial opening of Pandora's box.

Although CMS did not define what would be a "reasonable" practice restriction, it did note that it believes "any practice restrictions or conditions that do not comply with applicable State and local law run a significant risk of being considered unreasonable" (referring in particular to laws governing noncompete agreements).

Guaranty of Repayment by Group for Recruited Physician. CMS confirmed that the physician recruitment exception requires that the recruitment agreement be signed by the recruited physician, the hospital, and any practice receiving any part of the payments and that the hospital could require the physician practice to repay any monies advanced to the group on behalf of the recruited physician if the physician does not fulfill his or her community service requirement. CMS cautioned, however, that use of such a requirement to shield the recruited physician from any real liability for failure to fulfill his or her community service obligation would raise significant fraud and abuse concerns, particularly if the hospital failed to collect any amounts owed by the group under the guaranty. Given these concerns, hospitals may want to avoid asking the host group for a guaranty of repayment and limit their recourse against the host group to collection of the accounts receivable of the group that arise from the services performed by the recruited physician or take care in documenting collectability issues if payment is sought from the group instead of the recruited physician.

Nonconforming Agreements. CMS expressly rejected commenters' requests for grandfathering pre-existing physician recruitment arrangements entered into prior to the Phase II interim final rule. Instead, CMS took the highly aggressive position that any arrangement in effect on July 26, 2004 (the effective date of the Phase II rule) "should have been amended to comply with Phase II, whether the arrangement was in a payout period or in a forgiveness period." (emphasis added). CMS' logic on this point seems highly questionable. If the financial assistance had already been provided, and the physician or group practice was in compliance with the terms of the agreement, it is unclear what remuneration passed to the physician or group after the effective date of the Phase II rule. In essence, this seems to be an attempt by CMS to rewrite history and impose an impossible standard on providers not of knowledge, but foreknowledge.

Nonmonetary Compensation

CMS confirmed that hospitals exceeding the dollar limit for nonmonetary compensation will have a limited opportunity to undo the payments and remain in compliance. The excess amount cannot be more than 50% of whatever the current dollar value limit is for the nonmonetary compensation exception (\$329 in 2007), the excess amount must be repaid by the earlier of the end of the calendar year in which it was received or within 180 days, and the repayment option can only be used once every three years with respect to the same referring physician. 42 C.F.R. § 411.357(k)(3). This new correction opportunity will put an added premium on hospitals closely and promptly tracking the value of physician gifts if they need to rely on the nonmonetary compensation exception. In addition, CMS may argue that the specific relief provision for correcting excess nonmonetary compensation up to 50% precludes any arguments that a return of excess nonmonetary benefits in the same year wholly unrings the bell. In other words, once the dollar value limit is exceeded by more than 50%, CMS seems likely to take the position that any repayment, regardless of when made, does not avoid a Stark Law violation.

Phase III also added another exception for the cost of a single "local medical staff appreciation event per year for the entire medical staff." The cost of such events would not count toward the dollar limit for the nonmonetary compensation exception; however, any "gifts or gratuities" that are provided in connection with the event would count toward that limit. 42 C.F.R. § 411.357(k)(4). This new add-on to the nonmonetary compensation exception should ease the recordkeeping requirements for hospitals that sponsor an annual medical staff dinner or similar event.

Fair Market Value Compensation

In Phase III, CMS broadened the scope of the fair market value compensation exception by allowing payment "from" a physician as well as payment "to" a physician to qualify under this exception. However, CMS also limited the scope of the fair market value compensation exception by providing that it does not apply to protect the rental of office space between a physician, immediate family members, or physician group and a DHS entity. Although CMS took the same position in the preamble to the Phase II rule (69 Fed. Reg. at 16,086), it has now incorporated that position into the regulations. Equipment leases, however, still may be protected by the fair market value compensation arrangements exception.

Medical Staff Incidental Benefits

The only substantive change to this exception was to clarify that the benefits must only be "offered" to all medical staff members in the same specialty, not that all of them must actually receive or accept it. It may, however, be important to track who actually did receive a particular benefit to the extent that the number of recipients is relevant to determining the cost allocation per physician (e.g., for items not

individually priced or not returnable by the hospital). 42 C.F.R. § 411.357(m)(1).

Compliance Training

The only substantive change to this exception was to clarify that the mere qualification of a compliance course for continuing medical education (CME) credit does not take it outside of the exception. Rather, providing that course still can be within the compliance training exception if the primary purpose of the program is to provide compliance training. Although a minor change perhaps, this provision indicates some level of understanding by CMS that CME credit from compliance training is an incidental benefit to the physicians, and in fact may be practically necessary to induce attendance and improved education in compliance matters.

Malpractice Insurance

For all of the discussion about malpractice insurance subsidies of late, CMS did nothing in Phase III to expand the scope of malpractice insurance subsidies that may be protected. Consequently, any hospitals that subsidize physician malpractice insurance programs need to consider carefully whether they fit the limited exception for coverage for certain OBs or fit clearly within another Stark Law exception (e.g., employment, personal services arrangements, fair market value compensation arrangements). CMS even refused to extend the current exception to other specialties or to practices outside of a HPSA or to situations where a hospital is responding to evidence of community need, declaring community need to be “too ambiguous a standard and [one that] does not, by itself, eliminate the potential for program or patient abuse.”

Retention Payments

Although the retention payments exception is still limited to retaining physicians practicing in certain shortage areas, CMS expanded the scope somewhat by accepting either practice in a HPSA or other area with a demonstrated need approved by CMS, or drawing 75% of their patients from a medically underserved area or a medically underserved population. CMS also no longer would require a written offer for the retention payments exception. If a hospital is willing to conduct in-depth due diligence to verify an offer, it may rely on the physician’s certification as to the details of the offer without obtaining a written copy. The certification/due diligence option may increase flexibility, but it also may open up hospitals to second-guessing from CMS on the extent and results of the hospitals’ due diligence reviews.

Conclusion

CMS designed Phase III to “preserve the core [self-referral] prohibition, while providing sufficient flexibility to minimize the impact of the rule on many common business arrangements.” CMS states that Phase III accomplishes this goal by simplifying the Stark Law regulations, while providing additional compliance guidance in response to comments received after Phase II. CMS believes that the result will be to reduce the regulatory burden on the healthcare industry, but the flexibility that Phase III provides may be a mixed blessing.

Additionally, CMS repeatedly reminds the reader that the Stark Law is a strict liability statute with no intent requirement. In that regard, the flexibility that Phase III adds may result in a greater burden for hospitals and physicians from a defense perspective, as there are more open-ended variables to consider, document, and debate. For real-life illustrations of these risks, one need look no further than the latest issue of any number of industry publications to read about the latest qui tam suit, or an OIG

or Department of Justice investigation that could spill over into allegations of Stark Law violations. Increasing disclosure requirements from the IRS on the redesigned Form 990 will only fuel this fire. As referenced above, CMS is also adopting something of a “correspondence audit” approach to investigating Stark Law compliance, as evidenced by the Disclosure of Financial Relationships Report (DFRR). The DFRR is a detailed questionnaire on financial relationships that CMS will mail to 500 hospitals in September 2007. Ignoring the DFRR is not an option (or, at least, not an attractive option because doing so carries fines of \$10,000 per day for late responses), and hospitals that receive a DFRR have only a 45-day period in which to respond. CMS intends to make the DFRR an annual reporting requirement for hospitals.

The DFRR clearly states that one purpose of gathering the information is to assess hospitals’ compliance with the Stark Law. With the advent of Phase III, the new self-reporting program and potential additional Stark Law regulations looming when the MPFS Proposed Rule becomes final, CMS has created a new environment for Stark Law compliance that targets perceived abuse and is even more likely than before to require self-disclosure of such abuse, at least for hospitals receiving disclosure forms from CMS.

View the chart [*Cumulative Summary of Key Stark Law Regulatory Reforms \(Pending and Proposed\)*](#).

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[1] For a detailed discussion of the impact that the MPFS Proposed Rule could have on common hospital-physician joint ventures, see *Stark on the Fast Track: Separate Rulemaking Threatens Many Common Deals*, available at http://www.jonesday.com/pubs/pubs_detail.aspx?pubID=S4540.html.

[2] Having a majority community board is in fact the IRS preference under the community benefit standard (*see, e.g.*, Rev. Rul. 69-545); however, the IRS has approved exemption applications for faculty practice plans and captive or friendly professional corporations with 100% physician boards when there are other means of control and accountability, such as outside approval of physician compensation or significant reserved powers for the affiliated hospital and restrictions on transfers of stock, dividends or realizing appreciation on the stock.

[3] The regulations are not specific as to whether this same limitation applies to the requirement that a majority of admissions come from faculty physicians.

[4] The physician recruitment exception also will apply in the same fashion to both federally qualified health centers and rural health clinics under the Phase III rule.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
<p>Academic Medical Centers</p>	<p>The existing AMC exception requires, among other items, that the “total compensation” paid by “all academic medical center components” to referring physicians be set in advance, consistent with fair market value for the services provided, and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.</p>	<p>None.</p>	<p>Phase III makes clarifying changes to the AMC exception, such as:</p> <ul style="list-style-type: none"> ▪ Making clear that the “total compensation” paid to a referring physician should be determined based on the aggregate amounts paid by all components of the AMC; ▪ Expressly recognizing that the written documentation necessary to establish an AMC may be contained in one or more written agreements or other documents adopted by the governing body of each AMC component; and ▪ Imposing a new limitation on the ability to count volunteer and courtesy faculty in determining “faculty members” by requiring hospitals to count all physicians with the same class of privileges. 	<p>The clarifications should ease concerns over compliance with the AMC exception’s compensation provisions, while also providing more organizations, which have evolved over time, with greater certainty of their AMC status for Stark Law purposes. Phase III may, however, require a reduction in non-faculty physicians holding courtesy or other secondary privileges.</p>

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Alternative Methods of Compliance	No rule presently exists by which parties may cure technical violations of the Stark Law that result from a failure to adhere to form requirements, such as the failure to obtain a signature on a lease agreement.	CMS solicited comments on whether it should adopt rules allowing for alternative methods of compliance for technical violations of form. Significantly, CMS indicated that, if it adopts such a rule, parties must notify it of violations and allow CMS to determine (in its sole discretion and without appeal) whether the violation resulted from a failure to follow form requirements as opposed to more substantive violations, such as paying compensation that exceeds fair market value.	Phase III does not address alternative methods of compliance. Instead, it notes that, because the Stark Law is a strict liability statute, it cannot except “minor” or “technical” violations. Still, CMS states that it is supportive of adopting additional exceptions that do not present a risk of Medicare abuse.	While CMS acknowledges that alternative methods are necessary, the requirements it enumerated as part of the MPFS are likely too burdensome and time-consuming to be of much benefit to hospitals or physicians.
Applicability of Medicare Billing Regulations	The Stark Law regulations state that they do not affect the application of any other state or federal law.	None.	Phase III states explicitly what the existing regulations imply – that the Stark Law regulations do not create any exceptions to existing Medicare billing rules, such as the reassignment provisions.	None.
Burden of Proof	No rule presently exists on who carries the burden of proof for establishing that a claim for DHS resulted from a prohibited referral.	After a claim is denied as a result of Stark Law violations, the burden of proof would be on the entity submitting the claim for payment to establish that it did not result from a prohibited referral.	None.	The MPFS proposal emphasizes the documentation burden for DHS entities and sets the stage for ongoing correspondence audits of Stark Law compliance.
Compliance Training	The compliance training exception may not be utilized for programs that provide continuing medical education (CME).	None.	Phase III would allow the compliance training exception to be used for programs that qualify for CME credit, provided that compliance training is the primary purpose of the program.	The regulatory change will likely assist hospitals in ensuring that the incidental benefits provided to medical staff members comply with the Stark Law.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
DHS “Entity”	Regulations currently state that an “entity” for Stark Law purposes includes only the person that bills for the DHS.	The term “entity” would include both the person who performed the DHS and the person who bills for it.	None.	With a limited statutory exception for pre-12/19/89 group practice deals, the MPFS proposal would prohibit physician ownership in joint ventures that provide services to hospitals under arrangements, unless the entity is a rural provider.
Downstream Contractors	Regulations currently refer to “downstream subcontractors” for purposes of certain Medicare managed care arrangements.	None.	Phase III deletes the reference to “downstream subcontractors” and replaces it with “downstream contractors” – a new term that encompasses the individual or entity that contracts with the managed care organization and the subcontractors of that person or entity.	None.
Fair Market Value Safe Harbor	Regulations currently contain a safe harbor that allow parties to use compensation surveys to establish that an hourly rate is consistent with fair market value.	None.	Phase III eliminates the safe harbor under the guise that doing so will provide added flexibility to physician-hospital relationships.	Eliminating the safe harbor should not achieve any additional flexibility—fair market value for Stark Law purposes was not limited by the safe harbor. Phase III merely deprives parties of a safe harbor to ensure that their relationships are consistent with fair market value.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Incident to Services	Existing Stark Law regulations contradict each other regarding what services or supplies may be performed on an "incident to" basis." For example, the regulations define "incident to" services to exclude those services or supplies, such as diagnostic tests, that are covered by a separate Medicare benefit category. Yet the definition of "physician services" specifically references diagnostic tests as an "incident to" service.	None.	Phase III clarifies that "incident to" services do not include services or supplies covered by a separate Medicare benefit category, and deletes the contradictory reference found in the definition of "physician services."	CMS previously signaled that it would make this change as part of Phase III. Group practices should review their compensation formulas to ensure that they do not base productivity bonuses directly on services or supplies covered by separate benefit categories (such as x-rays and other diagnostic tests).

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
<p>Indirect Financial Relationships (“Stand in the Shoes” Approach)</p>	<p>Parties must analyze relationships first to determine whether an indirect compensation arrangement exists and, if so, whether the arrangement falls within a special exception for indirect compensation arrangements. Under current regulations, however, a physician is deemed to stand in the shoes of his or her solely owned practice and cannot rely on the indirect compensation arrangements definition or exception.</p>	<p>CMS proposed that, where a DHS entity owns or controls an entity to which a physician refers patients for DHS, the DHS entity 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.</p>	<p>Phase III essentially adopts the same rule that CMS proposed as part of the MPFS, but with respect to physicians and “physician organizations,” such as a physician practice (but not including other entities such as leasing companies). When a physician organization is all that stands between a physician and a DHS entity, the physician will be deemed to have a direct financial relationship with the DHS entity and must satisfy a Stark Law exception. Phase III also provides limited grandfathering protection for indirect compensation arrangements in situations involving a chain that has a physician organization as the only intermediate link to the referring physician, with the grandfathering limited to the arrangement’s current term.</p>	<p>The combined effect of these proposals would make indirect compensation arrangements less complicated to analyze for Stark Law purposes. However, the Phase III narrowing of the definition of indirect compensation arrangements and elimination of the exception for indirect compensation arrangements through physician organizations will require physician practices to examine each of their relationships to ensure that these relationships satisfy other Stark Law exceptions. CMS also is considering further limitations on indirect compensation arrangements, including physician-owned leasing companies.</p>

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
In-Office Ancillary Services Exception	Stark Law regulations allow physicians or group practices to provide DHS (other than most DME and parental and enteral nutrients, equipment and supplies) if the provision of such services satisfies supervision, building and billing requirements.	<p>CMS solicited comments on:</p> <ul style="list-style-type: none"> ▪ Whether certain services should not qualify for the exception; ▪ Whether it should modify the definitions of “same building” and “centralized building” and, if so, how; ▪ Whether non-specialist physicians should use the exception to refer patients for specialized services involving equipment owned by the non-specialists; and ▪ Any other restrictions on ownership or investment in services. 	Phase III makes no substantive changes to the in-office ancillary services exception. However, CMS states that, while it lacks the ability to repeal the exception, it is considering whether certain arrangements – specifically in-office pathology labs and imaging equipment – should not qualify for its protection.	CMS acknowledges that the in-office ancillary services exception is statutory, but may propose a narrower version based on CMS’ interpretation of Congressional intent as protecting only services necessary for the diagnosis and treatment of whatever brought the patient into the physician’s office.
Intra-Family Rural Referrals	Regulations establishing the exception for intra-family rural referrals require that no other person or entity (other than the referring physician’s family member) be “available” within 25 miles of the patient’s residence.	None.	Under Phase III, the exception may be utilized when other DHS providers are located within 25 miles of the patient’s residence, but more than 45 minutes travel time (considering distance, posted speeds and weather conditions) from the patient’s residence.	While clarifying the exception for physicians in rural areas, the new flexibility does not establish any bright line test upon which they may rely. CMS also stated that physicians choosing the 45-minute test should maintain documentation of how they calculated travel time for each intra-family referral.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Medical Foundations	Present Stark Law regulations do not provide that all medical foundations qualify as group practices.	None.	Phase III does not make a blanket determination that all medical foundations qualify as group practices. However, "[i]n States in which a foundation (or other corporation) may provide physician services, a medical foundation may be a group practice if all of the group practice requirements are satisfied."	According to CMS, "[w]ith the new 'stand in the shoes' provision ..., many arrangements involving foundation-model structures may be deemed to be direct compensation arrangements and potentially qualify for the personal service arrangements exception."
Noncompliant Financial Relationships	No regulation addresses how long CMS will disallow claims for DHS when a financial relationship fails to comply with a Stark Law exception.	CMS did not propose any specific rule, but stated that, generally, the period of disallowance would begin on the date that the financial relationship failed to comply with an exception and end on the date that the relationship ended.	None.	CMS has requested comments, in conjunction with the MPFS, as to whether it should create rules for determining when a financial relationship has terminated. In attempting to establish such bright line rules, CMS may inadvertently penalize providers excessively for failures of form.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Non-Monetary Compensation	DHS entities may provide physicians with items or services having a value of up to \$300 per year, as adjusted for inflation.	None.	Phase III clarifies that the dollar amount limit applies on a calendar year basis. It also offers physicians and DHS entities an opportunity to cure the payment of excessive non-monetary compensation. If the value of the excessive non-monetary compensation is no more than 50% of the annual limit, the parties may avoid Stark Law liability by having the physician repay the excess by the earlier of the end of the calendar year in which it was received or within 180 days from its receipt. The repayment provision can be used only once every three years for the same physician.	Phase III takes a practical approach by allowing physicians to repay excessive non-monetary compensation. However, it is not clear how this provision will operate in practice, such as when does the time begin running for repayment if the physician receives one item that exceeds the \$300 limit and then receives a second item two weeks later that increases the amount that must be repaid.
Obstetrical Malpractice Insurance Subsidies	The current exception requires that the subsidy meet all elements of the safe harbor to the Federal Anti-Kickback Statute.	CMS did not propose any specific revisions to the exception. Instead, CMS sought comments on what provisions of the safe harbor are necessary to protect against program or patient abuse.	None.	The present exception affords little benefit to physicians and hospitals in markets where malpractice coverage costs have increased. When it finalizes the 2008 MPFS, CMS may relax the exception's requirements to ensure that beneficiaries have access to obstetrical services.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Personal Services Arrangements	The existing exception for personal services arrangements does not provide any flexibility to parties who fail to renew an agreement prior to its expiration, but continue to act in accordance with the expired agreement's provisions.	None.	Phase III adopts a "holdover" provision that allows the parties to continue in compliance with the exception for up to 6 months following the expiration of an agreement that previously satisfied the exception, so long as they continue to act in accordance with the expired agreement's terms and conditions.	The revision provides additional, needed flexibility for physician-hospital relationships.
Physician in the Group Practice	Stark Law regulations currently define a "physician in the group practice" as including an independent contractor during the time that he or she furnishes patient care services for the group practice under a "contractual arrangement" with the group practice. The current regulations do not expressly prohibit the use of an indirect contractual arrangement.	None.	Phase III modifies the definition of a "physician in the group practice" to require the independent contractor physician to have a contractual arrangement directly with the group practice.	This new requirement may prevent practices from counting physicians providing turn-key or under arrangements services (also typically contracted through entities) as "physicians in the group," potentially threatening compliance with the in-office ancillary services exception.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Physician Recruitment	The existing exception for physician recruitment arrangements requires that, when a recruited physician joins an existing practice, the practice may not place restrictions on the physician's ability to practice, except for those related to quality of care.	None.	Phase III allows an existing practice to impose restrictions that do not "unreasonably restrict" the recruited physician's ability to practice. The commentary makes clear that, depending on the scope, non-compete provisions and liquidated damages clauses will not automatically be deemed to violate the terms of the exception. Additionally, the commentary provides examples of other terms that do not "unreasonably restrict" the ability to practice, such as non-solicitation provisions. Moreover, Phase III provides greater flexibility with respect to the relocation requirements of the exception, and, for practices in a rural area or HPSA replacing retired or deceased physicians, limited relief from the requirement that funds provided to a group practice not be used to offset more than the "additional incremental costs" attributable to the physician.	Phase III loosens to the restrictive nature of the physician recruitment exception. However, these changes – such as a group practice's ability to impose reasonable restrictions on a recruited physician, likely create greater ambiguity than that which previously existed.
Physician Retention Payments in Underserved Areas	The regulations permit the offer of retention payments only if the physician has a bona fide written offer to leave the underserved area.	None.	Phase III relaxes the requirement for a written offer by stating that the physician need only have an "offer of employment"; however, the physician must provide a detailed written certification and the hospital must take reasonable steps to verify the offer and its terms.	Phase III makes the exception slightly more beneficial by allowing hospitals to act more quickly to retain physicians. However, the difference in timing between an offer being presented orally and one reduced to writing with a verification process is likely to be minimal, and the latter may take longer.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Productivity Bonuses for “Incident to” Services	The Stark Law regulations currently allow group practices to pay physicians in the group a productivity bonus or profit sharing based on personally performed services and services incident to such personally performed services.	None.	Phase III clarifies the regulatory text by stating that the group practice may pay a productivity bonus, but not profit sharing, based directly on a physician’s personally performed services and those services incident to his or her personally performed services.	The clarification in the regulatory text is not likely to have a significant effect on group practices that pay productivity bonuses based on personally performed services or services incident to personally performed services. It may, however, require minor adjustments to some profit distribution formulas.
Retirement Plan Interests	Ownership and investment interests do not include an interest in a retirement plan.	CMS has proposed modifying the retirement plan exclusion to tie it more directly to employment relationships.	None.	The proposed rule would exclude interests in a retirement plan only if offered to the physician (or his or her immediate family member) through the physician’s (or family member’s) employment.
Security Interests	Existing Stark Law regulations state that ownership or investment interests may be through “equity, debt or other means.” The existing language created the possibility that a security interest in equipment sold to a DHS entity would result in an ownership or investment interest in the entity for which no Stark Law exception would be available.	None.	Phase III creates a limited exception for security interests held by a physician in equipment sold to a hospital that results from the physician financing the hospital’s purchase of the equipment. Loans or bonds tied to a particular department or discrete hospital operation, however, still would create ownership or investment interests.	The exception that Phase III creates applies only to equipment sold by a physician to a hospital. This means that CMS may have inadvertently created additional questions regarding whether security interests retained in equipment sold to non-hospital DHS entities results in an ownership or investment interest.

Cumulative Summary of Key Stark Law Regulatory Reforms (Pending and Proposed)

Topic	Existing Regulation	2008 Medicare Physician Fee Schedule (MPFS) Proposal	Phase III Regulation	Impact on Physician-Hospital Relationships
Set in Advance (Percentage-Based Compensation)	Percentage-based compensation is considered set in advance if the formula for calculating it is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid.	CMS has proposed clarifying that percentage based compensation arrangements may be used to pay for personally performed physician services only and must be based on the revenues directly resulting from the physician services, rather than other factors, such as percentage of the savings generated in a hospital department.	None.	If finalized, the proposal would require hospitals and physicians to examine their relationships to ensure that percentage-based compensation is used solely for personally performed physician services.
Unit-of-Service ("Per Click") Lease Arrangements	"Per click" compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for the services or items actually provided and does not vary during the course of the agreement in any manner that takes into account referrals of DHS or other business generated by the referring physician.	The proposed rules would disallow "per click" arrangements to the extent that the lease charges reflect services to patients referred by the lessor to the lessee. CMS has requested additional commentary on whether it should impose a corresponding prohibition on "per click" arrangements for referrals from the lessor to a physician lessee.	Phase III does not address "per click" compensation directly. Instead, CMS provides commentary that strongly suggests "per click" leases cannot satisfy the exclusive use requirements of the office and equipment lease exceptions.	The MPFS proposal, together with the Phase III commentary, signal a clear intent by CMS to eliminate all "per click" lease arrangements.