

CMS Publishes Phase III Stark Law Rule

September 2007

Introduction

On September 5, 2007, the Centers for Medicare and Medicaid Services (CMS) published the long-awaited third phase of its final rulemaking (the Phase III rule) regarding the federal physician self-referral prohibition, known as the “Stark law.”¹ In this White Paper, we refer to the regulations, as promulgated and amended by the Phase I (published January 4, 2001), Phase II (published March 26, 2004) and Phase III rules as the Stark Law regulations. In the interest of heading off future confusion, we note that the phases of CMS rulemaking regarding the self-referral prohibition should not be confused with the two principal legislative acts that enacted the prohibition, known as Stark I (which was applicable only to clinical laboratory services) and Stark II (which expanded the prohibition to the current list of designated health services). To date, no Stark III legislation has been enacted.

The amendments reflected in the Phase III rule go into effect on December 4, 2007. CMS also has republished the entire Stark Law regulations in the Federal Register. The Phase III rule contains some revisions that will be welcomed by physicians and entities furnishing designated health services subject to the self-referral prohibition (designated health services (DHS) entities). Other provisions of the Phase III rule are likely to prove problematic. We note at the outset, however, that CMS has not further restricted permitted financial relationships with, and interests held by, physicians, as it suggested it might in the recently published proposed Medicare physician fee schedule regulations (“2008 Proposed Fee Schedule Rule”).² See the McDermott White Paper titled *Proposed Medicare Rule Would Restrict Permitted Business Arrangements*, published July 10, 2007, at <http://www.mwe.com/info/news/wp0707a.htm>.

CMS also took this opportunity to clarify by explicit regulation that the Stark Law regulations must be complied with in addition to all other applicable regulatory requirements, and that the Stark Law regulations do not alter an individual’s or an entity’s obligations regarding reassignment of claims, requirements for purchased diagnostic tests, payment for services and supplies incident to a physician’s professional services, or any other Medicare statutory or regulatory obligations. Although compliance with the Stark Law regulations may be complicated by simultaneous compliance with other regulatory requirements, or vice versa, compliance with the Stark Law rules does not excuse compliance with other Medicare or Medicaid requirements, including the anti-kickback statute.

Although we have summarized the key provision of the Phase III rule, we commend the entire regulatory preamble and text to those interested in further interpretation of the Stark Law regulations.

Group Practice Compensation: “Incident To” Services and Special Rule for Productivity Bonuses and Profit Shares

It is well established that group practices receive more flexible treatment under the Stark Law with respect to physician compensation than other DHS entities. Unlike other DHS entities, a group practice may pay a physician in the group a share of the group’s overall profits or a productivity bonus based on services personally performed or services “incident to” such personally performed services, as long as the profit share or bonus is not determined in a manner that is directly related to the volume or value of the physician’s referrals. Prior to Phase III, however, the application of some of these concepts remained in question. CMS used Phase III as an opportunity to clarify these and other important issues surrounding physician compensation in a group practice.

First, CMS states that, in Phases I and II, it did not intend to distinguish between “services” and “supplies” furnished “incident to” a physician’s professional services. Accordingly, Phase III revises the definition of “incident to” services in Section 411.351 to clarify that the term includes both services and supplies that meet the requirements of “incident to” services under applicable Medicare rules. Thus, the Phase III amendment conclusively validates that a physician in a group practice may receive a productivity bonus for supplies (including drugs), assuming that they properly qualify and are billed on an “incident to” basis.

Second, CMS reiterates in Phase III that unless a statutory exception applies, only those services that do not have their own separate and independently listed benefit category may be billed as “incident to” a physician service. Phase III expressly deletes Section 411.355(a)(3) in order to eliminate any misconception that diagnostic tests can qualify as “incident to” services. As a result, x-ray tests, laboratory tests and other diagnostic tests—all of which comprise a single benefit category under applicable

¹ 72 Fed. Reg. 51012, September 5, 2007

² 72 Fed. Reg. 38122, July 12, 2007

Medicare rules—may not be billed as “incident to” services. Although CMS addressed this specific issue in the preamble to Phase II, certain regulatory text set forth in Section 411.355(a)(3) suggested otherwise.

The Phase III revised regulatory text also makes clear that productivity bonuses can be based directly on “incident to” services that are incidental to the physician’s personally performed services, even if those “incident to” services are otherwise DHS referrals (*e.g.*, outpatient prescription drugs). This is of critical importance for purposes of determining the method of calculating a physician’s compensation in many group practices, particularly with regard to productivity bonuses.

In connection with the revisions discussed above, CMS also expressed its intent to minimize any perceived inconsistencies between the Stark law, CMS’s statutory definition of “incident to” services, the “incident to” billing rules and the relevant Medicare manual provisions. Doing so presents some clear challenges, especially in connection with two common group practice ancillary services—physical therapy and diagnostic tests.

For example, if physical therapy is provided on an “incident to” basis, a group practice physician must be present in the office suite where the physical therapy is being provided. In such instances, the physical therapy ancillary revenue can be allocated directly to the treating physician. However, many group practices provide physical therapy services without a physician present on the premises.

In both instances, the services qualify for the in-office ancillary services exception. In the latter instance, however, the physical therapy revenue cannot be allocated directly to the treating physician, but instead must be handled in a manner that complies with the Stark law special rules regarding physicians receiving a productivity bonus or an overall share of profits.

With regard to diagnostic tests, CMS has now unequivocally expressed that Medicare-covered imaging services that are DHS cannot qualify as “incident to” services, and thus should not be credited by a group practice to the ordering physician under a productivity-based compensation methodology. In other words, a group practice cannot provide a group practice physician who ordered a diagnostic test with a productivity bonus directly related to such test, on the basis that such diagnostic test was provided as “incident to” other services rendered by the ordering physician.

This, however, will not prevent a group practice physician (including the ordering physician) from receiving credit for personally performed services, including professional interpretations of diagnostic tests performed by the physician. Professional interpretations increasingly are being performed by cardiologists, neurologists and other specialists in a group practice setting, often in connection with another physician in the group practice who provides the requisite supervision, and an over-read provided by an off-site radiologist.

Thus, unless the ordering physician also personally performed the physical therapy or imaging service (which is uncommon), then (i) in such instances where the physical therapy does not qualify as an “incident to” service, and (ii) in all cases of the technical component revenue from diagnostic imaging, such ancillary revenue cannot be allocated directly to the ordering physician. Rather, a group practice must rely on the special rules on compensation to pay the group practice physician a profit share and productivity bonus that indirectly relates to such DHS referrals (*e.g.*, based on relative professional revenue, patient encounters or relative value units (RVUs)).

Elimination of Safe Harbor Method for Establishing Fair Market Value of Personal Services

In the Phase II rule, CMS created a “safe harbor” method of establishing that compensation for physicians’ personal services was at “fair market value” (FMV). The safe harbor provided two entirely voluntary methods for calculating hourly rates that would be deemed fair market value for purposes of the Stark Law. The first method limited the hourly payment to the average hourly rate for emergency room physician services in the relevant physician market, provided there were at least three hospitals providing emergency room services in the market. The second method was based on the average of the “50th percentile national compensation level for physicians in the same specialty,” using at least four of six specified salary surveys, and dividing the result by 2,000 hours to establish an hourly rate.

CMS eliminated the safe harbor method in the Phase III rule, based on numerous negative comments regarding the safe harbor method, the fact that one of the listed surveys no longer exists and another is out of date, and concerns regarding the availability of the surveys. CMS continues to stress FMV as an essential element of many of the Stark Law exceptions and to question reliance on appraisals for determining FMV, explaining that while “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." CMS continues to acknowledge that "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," but notes that "reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value."

"Stand in the Shoes"

The most far reaching change in the Phase III rule is the so-called "stand in the shoes" provision. Currently, if a DHS entity has a financial relationship with a physician's medical practice, the arrangement is not viewed as a direct compensation arrangement with the individual physician. Instead, if there is a chain of financial relationships involving at least one other entity interposed between the physician and the DHS entity, the arrangement is analyzed as a potential indirect compensation arrangement. This involves a two-step inquiry:

- (1) Is there an "indirect compensation arrangement" (a defined term) between the individual physician and the DHS entity? If not, the analysis ends at this step.
- (2) If there is an indirect compensation arrangement, does the arrangement meet the indirect compensation exception?

The Phase III rule has significantly narrowed the types of arrangements that will be subject to the indirect compensation analysis, by providing that a physician "stands in the shoes" of his or her "physician organization" (a new definition, discussed further below) for purposes of analyzing financial relationships. The "stand in the shoes" rule also will change the analysis for certain arrangements involving medical practices that remain subject to the indirect compensation analysis.

The "stand in the shoes" provisions are found in Section 411.354, which defines the various types of financial relationships. A new definition of "direct compensation arrangement" has been added, which includes the following:

A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.

The definition of "indirect compensation arrangement" also has been changed, in parallel fashion. It provides that, for purposes of determining whether there is at least one intervening entity between the physician and a DHS entity, "a physician is deemed to 'stand in the shoes' of his or her physician organization." Under the changed definition, certain arrangements that had been indirect will become direct. Other currently indirect relationships will remain indirect (*e.g.*, situations in which both a physician organization and another entity are interposed between a physician and a DHS entity). However, the analysis of whether there is an indirect compensation arrangement and whether it meets the indirect compensation exception may change, since the relevant compensation "link in the chain" to be reviewed may change when the physician stands in the shoes of his or her physician organization. Therefore, even arrangements that remain indirect should be reviewed for continued compliance.

A physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization itself. For purposes of applying the various exceptions for compensation arrangements, the parties to the arrangement are considered to be the DHS entity and the physician organization, *including all members, employees or independent contractor physicians*.

In many cases, the application of the new provisions is straightforward. For example, an office lease between a hospital and a medical group must comply with the lease exception, rather than the indirect compensation exception. A medical director agreement between a hospital and a medical group must comply with the personal services or fair market value exception. In the case of arrangements involving academic medical centers, the academic medical center exception may be available as well. In the cases of leases and personal service arrangements, the direct compensation exception is actually more intuitive and straightforward than the indirect compensation analysis, and also is consistent with the approach to such relationships under the federal anti-kickback statute. However, in other cases, including certain arrangements involving academic medical centers (discussed below), it is not as easy to apply a direct compensation exception. Also, certain "per click" leases between a physician

organization and a hospital will have to be restructured if the provisions of the 2008 Proposed Fee Schedule Rule relating to “per click” leases under the exceptions for space and equipment leases are implemented as proposed.³

The new definition of “physician organization” also raises some questions. A “physician organization” is “a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of §411.352 [group practice definition].” This definition and the discussion in the preamble indicate that “physician organization” is intended to include a physician’s medical practice as that term is commonly understood. The inclusion of the term “physician practice” in addition to “group practice” presumably is intended to ensure that the “stand in the shoes” rule extends to practice entities that do not meet the detailed and technical Stark Law “group practice” definition. CMS states that this “approach incorporates a commonsense understanding of the relationship between group practices and their physicians.” Based on this definition, physician investment vehicles that do not furnish physicians’ professional services would not fit the definition and therefore would not be subject to the “stand in the shoes” rule. However, the application of the definition of “physician organization” is not as clear with respect to other entities that employ physicians, but are not “physician practices” in the usual sense. For example, hospitals often employ physicians, but are not considered “group practices” for Stark Law purposes. Nevertheless, should a hospital that employs physicians be considered a “physician organization” for purposes of the “stand in the shoes” rule? What about a university or medical school? Considering a physician to stand in the shoes of such entity, thus making the physician in effect a party to all contracts of the entity, could enormously complicate the Stark Law compliance efforts of such entities.

Another question raised by the “stand in the shoes” provision is whether, when one physician organization contracts with another, the physicians in the first physician organization—or perhaps any physician whose services are provided pursuant to the contract—also stand in the shoes of the second physician organization. The “stand in the shoes” rule states that a physician stands in the shoes of “his or her” physician organization, but does not clarify the specific relationships that make a physician organization “his or her” physician organization. Arguably, only the physician organization that has a direct financial relationship with a physician qualifies as his or her physician organization. However, if, after applying the rule, the physician then is deemed to have a direct relationship with another entity that also qualifies as a physician organization, the question is raised whether the physician stands in the shoes of that physician organization as well. While we think that the “stand in the shoes” rule should be interpreted to apply only to a physician’s direct relationships (before application of the rule), a conservative approach would be to analyze potential Stark Law issues that may arise if a physician is deemed to stand in the shoes of both physician organizations in the example provided above.

CMS acknowledges that many arrangements in which only a physician organization is interposed between a DHS entity and a physician have been properly structured to comply with the indirect compensation exception. CMS states that “[i]t is not our intent to require that those arrangements be reexamined and revised to comply with a direct compensation arrangement exception.” Therefore, CMS has provided that the new “stands in the shoes” provisions do not apply “during the original term or current renewal term of an arrangement that satisfied the requirements of §411.357(p) [indirect compensation exception] as of September 5, 2007.”⁴ Although this “grandfathering” provision is helpful, it does not relieve parties from re-examining and revising their arrangements. CMS’s statement fails to recognize that many arrangements renew from year to year, and therefore it will be necessary to re-examine and restructure many ongoing arrangements at renewal, since the grandfathering only protects the current term. Also, the grandfathering will not apply to arrangements that were structured solely based on not meeting the definition of “indirect compensation arrangement” (*i.e.*, were deemed to be completely outside the Stark Law under the current definitions), and do not meet the indirect compensation exception. Arrangements involving academic medical centers will be particularly affected by the “stand in the shoes” changes.

Academic Medical Centers

While CMS contends that the Phase III rule in general will reduce the regulatory burden on the health care industry, the effect on academic medical centers (AMCs) is likely to be the opposite. Phase III introduces new ambiguities, limits the availability of certain exceptions, and creates new perils that innocuous and nonabusive arrangements will run afoul of the Stark Law.

³ See the McDermott White Paper titled *Proposed Medicare Rule Would Restrict Permitted Business Arrangements*, published July 10, 2007, at <http://www.mwe.com/info/news/wp0707a.htm>.

⁴ September 5, 2007, is the Federal Register publication date.

CHANGES TO ACADEMIC MEDICAL CENTER EXCEPTION

The Phase III rule provides some minor clarifications to the AMC exception. First, CMS notes that the requirement that faculty receive fair market value compensation is to be applied on an aggregate basis to all compensation from AMC components. This is a helpful clarification, since compensation may be divided between the medical school and the faculty practice plan in ways that do not necessarily comport with fair market value principles. Second, CMS clarifies that, in determining whether an AMC hospital satisfies the requirement that a majority of its medical staff be faculty members, the hospital is free to include or exclude certain classes of privileges (*e.g.*, courtesy privileges), but must then apply that approach uniformly to all physicians with such privileges. Third, CMS clarifies that the requirement that compensation not “take into account” referrals or other business generated for any AMC component is applied to each separate compensation arrangement between a faculty member and an AMC component.

EFFECT OF “STAND IN THE SHOES” APPROACH

The more significant changes result from the application of CMS’ “stand in the shoes” rule to AMCs. As noted above, a physician is now deemed to “stand in the shoes” of his or her physician organization, defined as a sole shareholder professional corporation, group practice or “physician practice.” Unfortunately, the new term “physician practice” is undefined. Separately incorporated faculty practice plans are likely to be viewed as a “physician practice,” even if they do not qualify as group practices, but what about medical schools and universities generally? If the university or medical school employs faculty to perform, among other things, clinical activities, or if it bills for physician services in its own name, there is at least a risk that it will be viewed as a “physician organization.”

One likely effect of this application is to cause AMCs that previously relied on an indirect compensation analysis to protect non-fair market value transfers among AMC components to be forced to satisfy the AMC exception. This exception creates many difficulties, including the following:

- Faculty practice plans cannot distribute ancillary revenues consistent with the group practice rules and still qualify for the AMC exception.
- Compensation from all AMC components to a faculty member must be set in advance.
- Any grants to faculty for research must be used exclusively to support research and teaching, and funds must be expended consistent with the terms and conditions of the grant. Stark Law compliance is thus made conditional on research grant accounting compliance.
- Compensation to voluntary faculty may create inadvertent Stark Law violations. For example, assume a university operates a medical school and clinical laboratories directly as operating divisions. Faculty clinical activities are conducted through a separately incorporated faculty practice plan. The university provides the faculty practice plan with medical office building space at less than fair market value. A voluntary faculty member is engaged by the practice plan as an independent contractor at fair market value to provide certain needed specialty services pursuant to a written agreement that meets the Stark Law personal services exception. Under these circumstances, any Medicare lab referrals by the voluntary faculty member to the University lab would violate the Stark Law. The voluntary faculty member stands in the shoes of the faculty practice plan; the lease between the University and the practice plan does not satisfy the lease exception; and the AMC exception is not available because the voluntary faculty member is not an employee of any AMC component.

RECRUITMENT ARRANGEMENTS

CMS clarifies that physicians engaged in post-residency training need not satisfy the relocation requirements of the recruitment exception, just as residents have not needed to since the Phase II rule. This may create greater flexibility for recruitment of fellows.

CMS’s discussion of AMC hospitals providing recruitment incentives to physicians who will practice through medical schools or faculty practice plans is less clear. On the one hand, CMS indicates that such arrangements may qualify under the AMC exception. On the other hand, CMS states in commentary that where recruitment incentives will pass to a “physician practice,” the recruitment exception alone is available. The net effect is to introduce ambiguity as to whether payments between AMC components to support physician recruitment must satisfy the recruitment exception. If so, recruited faculty supported by the

AMC hospital would need to relocate from outside the AMC hospital service area, and income guarantees could include only incremental expenses (which in the case of faculty practice plans may be comparatively small).

In sum, the potential Stark Law implications for AMCs of the seemingly modest Phase III rule changes are substantial, and AMCs should revisit their various arrangements for compliance with the revised regulatory framework.

Physician Recruitment

The Phase II rule's physician recruitment exception protects payments made by a hospital or a federally qualified health center (FQHC) that are intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital, in order to become a member of the hospital's or the FQHC's medical staff, if certain conditions are met. The Phase III rule liberalizes the recruitment exception in several respects.

The Phase III rule creates various additional exceptions to the Phase II rule's relocation requirement, which requires that (1) a recruited physician move his or her practice at least 25 miles, or (2) at least 75 percent of the physician's revenues are derived from services furnished to patients whom the physician has not seen in the three years preceding his or her relocation, unless the recruit is a resident or physician who has been in practice one year or less. The Phase III rule exempts from the relocation requirement a physician who, for the two years immediately prior to the recruitment arrangement, was employed on a full-time basis by a federal or state bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Department of Veterans Affairs, or facilities of the Indian Health Service, provided that the physician did not maintain a separate private practice in addition to such full-time employment. In addition, CMS may exempt from the relocation requirement those physicians whom CMS has deemed, in an advisory opinion, not to have an established medical practice comprised of a significant number of patients who are or could become patients of the recruiting facility. Although these additional exceptions are only available for a narrow segment of the pool of potential physician recruits, they are helpful because they avoid the need to rely on the speculative 75 percent of physician revenue test of the current relocation requirement.

The Phase III rule also expands the recruitment exception to more areas within a recruiting facility's service area, by amending the definition of "geographic area served by the hospital." The Phase II rule defined the term as the area composed of the lowest number of contiguous zip codes from which the facility draws at least 75 percent of its inpatients. Under the Phase III rule, when the hospital draws less than 75 percent of its inpatients from contiguous zip codes, the "geographic area served by a hospital" is the area comprised of all of the contiguous zip codes from which the facility's inpatients are drawn. In addition, the Phase III rule permits a hospital located in a rural area to determine the "geographic area served by the hospital" using an alternative definition that encompasses the lowest number of contiguous (or in certain cases, non-contiguous) zip codes from which the hospital draws at least 90 percent of its inpatients. Further, the Phase III rule permits rural hospitals to recruit physicians into an area outside the hospital's geographic service area, if it is determined through a CMS advisory opinion that the area has a demonstrated need for the recruited physician. These changes to the definition should be particularly helpful to rural hospitals in less densely populated areas.

In addition, under the Phase II rule's recruitment exception, payments made to physicians through existing medical groups, or made directly to physicians recruited to existing medical groups, are only protected if the hospital takes into account only the incremental costs associated with the recruited physician when calculating whether to pay and how much to pay under any income guarantee provision, and no additional restrictions are imposed on the physician, other than those relating to quality of care (*e.g.*, covenants not to compete are prohibited). Certain other conditions also must be met.

The Phase III rule addresses some of the objections that medical groups have about the Phase II rule by easing the requirements for recruitment into an existing medical group. First, the Phase III rule permits medical groups to impose non-competes and other practice restrictions, as long as the restrictions are "reasonable." CMS does not define "reasonable," but the preamble to the Phase III rule suggests that state law regarding restrictive covenants is an important source of guidance regarding the reasonableness of a restriction. In making this amendment, CMS recognizes that it is customary for medical groups to impose non-competes on group members.

Second, in the case of a physician who is recruited to replace a deceased, retiring or relocating physician who is a medical group member and located in a rural area or a health care professional shortage area (HPSA), the Phase III rule permits an income guarantee up to the lower of a per capita allocation, or 20 percent of the medical group's aggregate costs (if greater than the

incremental costs attributable to the physician). This limited revision reflects CMS's ongoing concern about medical groups using recruitment arrangements to inappropriately shift overhead expenses to hospitals.

Finally, the Phase III rule extends the exception to payments made by rural health clinics consistent with the requirements for a hospital or FQHC.

Physician Retention in Underserved Areas

The Phase II rule created a physician retention exception to protect payments from a hospital or FQHC to a physician in order to retain the physician in the facility's service area. The Phase III rule modifies the requirements of the exception in several respects, expanding the usefulness of the exception. First, the Phase II rule requires the geographic area served by the facility to be underserved as evidenced by either being (1) a HPSA (though not necessarily a HPSA for the specialty of the recruiting physician), or (2) deemed by the Secretary of HHS in an advisory opinion to be an area of "demonstrated need" for the physician. The Phase III rule also allows this underserved area requirement to be met if at least 75 percent of the physician's patients reside in a "medically underserved area" or are members of a "medically underserved population," as defined by the Bureau of Health Professions of the Health Resources Services Administration of the U.S. Department of Health & Human Services.

Second, the amended exception permits retention payments in the absence of a written recruitment offer or offer of employment from a hospital, AMC or physician organization under certain conditions. The physician must certify in writing that he or she has a *bona fide* opportunity for future employment that requires moving his or her medical practice at least 25 miles, and outside the geographic area served by the hospital. The physician's statement must include certain other information required by the Phase III rule. Further, the retention payment must not exceed the lower of (1) an amount equal to 25 percent of the physician's current annual income (based on no more than the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the facility would otherwise have to expend to recruit a new physician to the geographic area served by the facility to join the medical staff of the facility to replace the retained physician. Although this new exception to the written offer requirement does not permit the hospital to match the certified offer, it addresses the practical problem that a firm written offer may only be given by the recruiting organization after it is too late for the hospital to retain the physician.

Finally, like the physician recruitment exception, the Phase III rule allows rural health clinics to make retention payments consistent with the requirements for a hospital or FQHC.

Fair Market Value Exception

The fair market value exception is a regulatory exception created by CMS in the Phase I rule to address concerns about gaps in existing compensation exceptions. Currently, the exception applies to fair market value compensation paid *to* a physician (or immediate family member) or a group of physicians for any items or services, provided certain terms and conditions are met (the Regulatory FMV Exception). The Phase III rule makes two changes to the Regulatory FMV Exception. First, the exception will now apply to compensation paid *by* a physician (or immediate family member) or a group of physicians to a DHS entity, in addition to compensation by a DHS entity to referring physicians. Second, the exception will now exclude the rental of office space as an "item" covered by the exception.

APPLICATION TO PAYMENTS BY PHYSICIANS

The Stark Law has always had a statutory exception for payments *by* a physician to a DHS entity for the purchase of services or items, if the payment is consistent with fair market value (the Statutory FMV Exception). However, CMS became concerned that the Statutory FMV Exception could be used to evade the more stringent requirements of other compensation exceptions, such as the space and equipment rental exceptions. Thus, CMS amended the Statutory FMV Exception in the Phase II rule to limit it to compensation arrangements "not specifically excepted under" another exception.⁵ Consequently, by amending the Regulatory FMV Exception to apply to fair market value payments by referring physicians to a DHS entity, CMS has effectively substituted its more stringent Regulatory FMV Exception for the existing Statutory FMV Exception, as applied to those compensation arrangements not specifically addressed by another Stark compensation exception (e.g., arrangements whereby a physician practice purchases services or supplies from a hospital or other DHS entity). Unlike the Statutory FMV Exception, the

⁵ Note: The Phase III rule changes "not specifically excepted under" to "not specifically addressed by."

Regulatory FMV exception requires a written agreement and a stated term length, and the compensation must meet the Stark “set in advance” and “volume/value” standards. In addition, the Regulatory FMV exception includes the requirement that the compensation not violate the federal anti-kickback statute, generally viewed as one of the broadest and vaguest federal health care laws. Consequently, payments by physicians to DHS entities for services and items not specifically addressed by other compensation exceptions (such as the space and equipment lease exceptions) are at an increased risk of falling out of a Stark exception.

EXCLUSION OF OFFICE SPACE LEASE ARRANGEMENTS.

In the preamble to the Phase I rule, CMS stated that the Regulatory FMV Exception can be used as an alternative to any compensation exception that might be applicable. Here, CMS excludes office space rentals from the exception, because it believes that office space leases have been subject to abuse, and it is concerned that the more relaxed requirements of the Regulatory FMV Exception (as compared to the office space exception) might be exploited to advance abusive arrangements. In this regard, we note that, in the 2008 Proposed Fee Schedule Rule, CMS proposes to amend the office space and equipment rental exceptions to exclude per unit of service or “click” rental payments.⁶ In so doing, CMS expresses concerns that office space and equipment rental arrangements that use per unit of service or “click” rent may incentivize or reward the physician-lessor for referrals to the DHS entity-lessee.⁷ If the Regulatory FMV Exception also applied to office space leases, “click” fee office space arrangements could continue in reliance on the Regulatory FMV Exception, because this exception continues to permit per unit of service or “click” fees. Notably, CMS has not yet excluded equipment rentals from the Regulatory FMV Exception, but if CMS finalizes its proposed exclusion of “click” fees from the equipment rental exception, CMS presumably will exclude equipment rentals from the Regulatory FMV Exception in future rulemaking.

Nonmonetary Compensation Exception

The nonmonetary compensation exception (sometimes still referred to as the *de minimis* compensation exception) was created by CMS in the Phase I rule, and is designed for situations in which a DHS entity gives a referring physician non-cash items of value, such as gifts, meals, entertainment and gratuities. The exception applies to items and services (other than cash or cash equivalents) that do not exceed \$300 in value per year, as adjusted annually by the CPI-U (currently \$329). The exception only applies if the compensation is not solicited by the physician or the physician’s practice, the compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the DHS entity, and the compensation does not violate the federal anti-kickback statute.

The Phase III rule amends the nonmonetary compensation exception to:

- clarify that the annual aggregate nonmonetary compensation limit is to be applied on a calendar year basis;
- create a method whereby parties that inadvertently exceed the annual aggregate nonmonetary compensation limit can still qualify for the exception under certain circumstances (the Inadvertent Excess Fix); and
- permit a DHS entity with a formal medical staff to exclude from its calculation of the annual aggregate nonmonetary compensation the value of one local medical staff appreciation event (such as a holiday party) per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event, such as door prizes, must still be included in the calculation.

CMS also clarified in the preamble that the limit applies at the DHS entity level, not at the parent or health system level.

ONE PARTY PER YEAR AMENDMENT

The fact that a hospital or other DHS entity with a formal medical staff will no longer need to worry about the value of one local medical staff appreciation event per year is a welcome development for the hospital industry. In combination with the Inadvertent

⁶ See the McDermott White Paper titled *Proposed Medicare Rule Would Restrict Permitted Business Arrangements*, published July 10, 2007, at <http://www.mwe.com/info/news/wp0707a.htm>.

⁷ 72 Fed. Reg. 38182-83

Excess Fix, this relief should lower the risk of a hospital inadvertently exceeding the nonmonetary compensation limit and falling out of the exception.

THE INADVERTENT EXCESS FIX

This amendment addresses an increasingly prominent concern of the health care industry about the disastrous legal effect of inadvertent and temporary noncompliance with a Stark exception. There is an existing exception from the Stark prohibition for inadvertent and temporary lapses of compliance with a Stark exception⁸, but it expressly excludes the nonmonetary compensation exception. Consequently, the Inadvertent Excess Fix might prove useful to hospitals and other DHS entities that rely on the nonmonetary compensation exception to protect the various events, gifts, meals and other gratuities furnished to referring physicians.

The Inadvertent Excess Fix can be used if:

- the value of the excess non-monetary compensation is not more than 50 percent of the applicable limit (currently \$329);
- the physician returns the excess (or an amount equal to the value of the excess compensation) by the end of the calendar year in which the compensation was received, or within 180 calendar days of receipt of the non-monetary compensation, whichever is earlier; and
- the Inadvertent Excess Fix has not been used with respect to the physician who received the excess value in the last three years.

As a practical matter, the above limitations on the Inadvertent Excess Fix mean that those hospitals and other DHS entities that need the nonmonetary compensation exception should continue or increase efforts to monitor and track nonmonetary compensation (by physician), and train staff on the entity's compliance policies and procedures for gifts, meals, entertainment and other gratuities. Absent such monitoring and compliance activity, the DHS entity is less likely to discover the excess compensation in time to take advantage of this fix. Deliberate ignorance of excess nonmonetary compensation to referring physicians will not be a defense against liability predicated on a violation of the Stark Law.

Personal Services Exception

The personal services exception is applicable to payments by DHS entities to referring physicians for personal services outside the employment context. Like most other Stark compensation exceptions, the personal services exception requires that the arrangement be in writing for a term of at least one year. The Phase III rule adds to the personal services exception a hold-over provision like that found in the office space and equipment rental exceptions. If at the expiration of the term of a personal services agreement (that does not automatically renew), the physician (or immediate family member) continues to provide personal services without a new written agreement, the personal services exception will still apply during a six-month hold-over period, provided the arrangement between the referring physician (or immediate family member) and the DHS entity is on the same terms and conditions as the expired written agreement.

This new hold-over provision to the personal services exception functions like an exception for inadvertent and temporary noncompliance with the writing and one-year term requirements of the personal services compensation exception. Such noncompliance can occur on the expiration of a personal services agreement that does not automatically renew, but the parties continue to perform under the agreement after the expiration date. In such circumstances, this provision should give the DHS entity and referring physician the flexibility to continue the compensation arrangement on the same terms for up to six months while negotiating the terms of a new written agreement.

Charitable Donations by a Physician

The Phase III rule amends the exception for charitable donations by a physician to clarify that the donation may be neither solicited nor offered in any manner that takes into account the volume or value of referrals or other business generated between

⁸ 42 C.F.R. § 411.353(f)

the parties. For example, the exception would not apply to a situation where the offer of a donation or the amount of the offered donation is conditioned on referrals to the physician by the DHS entity.

Professional Courtesy Exception

The Stark exception for professional courtesies (*i.e.*, free or discounted health care services or items to a physician or the physician's office staff or immediate family members) is amended by the Phase III rule to apply only to DHS entities with a formal medical staff, and to eliminate the requirement that the DHS entity disclose to the insurer any professional courtesy that involves a waiver of patient cost-sharing obligations.

Compliance Training Exception

The Stark exception for compliance training provided by a DHS entity to a physician practicing in the local community (or the physician's office staff) is amended by the Phase III rule to include compliance training for which there is continuing medical education credit, provided compliance training is the primary purpose of the program. Until now, continuing medical education had been expressly excluded from this exception, and no other Stark exception expressly permits a hospital to fund continuing education programs for members of their medical staffs. This amendment will give hospitals an opportunity to fund compliance training programs for which there is continuing medical education credit, which should increase medical staff interest in and attendance at such programs.

Security Interest, Not Ownership

In response to a comment on the Phase II rule, CMS amended the regulations to clarify that while "loans or bonds secured by, or otherwise linked to, a particular piece of equipment or the revenue of a department or other discrete hospital operations would be considered an ownership interest in part of a hospital," a security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital is not considered an ownership or investment interest in the hospital's assets, but would be a compensation arrangement for purposes of the Stark Law regulations. Accordingly, rather than representing an ownership interest in only part of a hospital, which would not be eligible for the "whole hospital exception," such an arrangement could qualify for the isolated transaction exception if all other requirements were satisfied.

CMS also clarifies in the Phase III preamble that a guaranty does not create an ownership interest, but usually would create a compensation arrangement for Stark Law purposes.

Physician Arrangements Through Retirement Plans

While the Phase III rule does not make any changes regarding physician interests in retirement plans, CMS took the opportunity to note that it has received anecdotal evidence regarding physicians who are purchasing ownership interests in DHS entities through their retirement plans, and that it does not consider such purchases to be consistent with the intent of the Stark Law. CMS further noted that to address this issue, it has proposed revisions to the Stark Law regulations in the 2008 Proposed Fee Schedule Rule. CMS cautioned that such situations may be part of an indirect compensation arrangement that would not satisfy the exception for indirect compensation arrangements, if the physician receives compensation from the retirement plan that takes into account the referrals to the DHS entity, and that such arrangements would also be problematic under the anti-kickback statute.⁹

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⁹ See the McDermott White Paper titled *Proposed Medicare Rule Would Restrict Permitted Business Arrangements*, published July 10, 2007, at <http://www.mwe.com/info/news/wp0707a.htm>.

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