



# HEALTH CARE FRAUD REPORT



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## Stark Phase II Final Rule: Summary and Analysis

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## I. INTRODUCTION

On March 26, 2004, the Department of Health and Human Services (“HHS”) Centers for Medicare & Medicaid Services (“CMS”) released the long-awaited second phase of the final regulation (the “Final Rule”) for the physician self-referral statute known as the “Stark Law.” The regulation itself is to be codified at 42 C.F.R. part 411, subpart J (§§ 411.350 – 411.361).

The Stark Law prohibits a physician from referring a Medicare or Medicaid patient to an entity for certain “designated health services” (“DHS”) if the physician (or an immediate family member) has a financial relationship with the entity unless the financial relationship falls completely within one of several exceptions.<sup>1</sup> Financial relationships are generally classified as either ownership or investment interests or compensation arrangements. In general, the Stark Law creates *per se* ownership prohibitions if an ownership exception is not met, whereas compensation arrangements are regulated through highly prescriptive compensation exceptions. As a result of this approach, the Stark Law does not necessarily prohibit referrals, but rather, it *regulates* self-referrals.

As explained in Section I.B below, the first phase of the Final Rule (“Phase I”) contained initial parts of the final rule and was published on January 4, 2001. This second phase of the Final Rule (“Phase II”), which comes with a 90-day comment period, will become effective on July 26, 2004. At that time, the Stark Law, close to 15 years since its enactment in 1989, will become fully implemented for referrals for Medicare covered DHS.

Our approach in preparing this Summary and Analysis has been to discuss various sections of the rule thematically and to devote separate sections to important exceptions. For example, the first exception we discuss is for indirect compensation, which we combine with a discussion of the definition of that term. Next, in Section VI we group together all of the remaining excep-

<sup>1</sup> In the interest of brevity, we will not further discuss the impact on physicians’ immediate family members, except for the Intra-Family Rural Referral exception discussed in Section X.D below.

tions that relate to physician compensation, even though in some cases, for example with group practices and academic medical centers, we only discuss the compensation provisions of those exceptions, leaving our discussion of other provisions of these exceptions for other sections. We have attempted to provide readers with appropriate cross-referencing where relevant and to indicate where the Phase II discussion relates to matters raised in Phase I.

We note that even a brief reading of this Summary and Analysis will make abundantly clear the complex nature of the Stark Law and Final Rule. This Summary and Analysis is intended to aid providers and their counsel in obtaining a preliminary overview of the issues raised in the Stark Law and the Phase II Final Rule, but **none of the information or analysis contained herein should be construed as providing legal advice, and we expressly reserve the right to advocate any interpretation of the Stark Law on behalf of our clients.**

#### A. CMS's Approach to Drafting the Final Rule

Following its approach in Phase I, in Phase II CMS has attempted "to reduce the burden and prescriptive nature" of the Stark Law and "clarify and simplify" the Phase I Final Rule, while at the same time preserving Congress' fundamental intent to reduce the influence of financial arrangements on physician referral decisions. In addition, CMS has used its limited statutory authority to create new exceptions, but only where it has determined that there is "no risk of abuse." CMS has also sought to balance the provider community's need for clear "bright-line" rules against the competing need for flexibility and practicality in application of the statute's restrictions.

#### B. Phases I, II, and III

Phases I and II are final rules based on the January 1998 proposed rule (the "Proposed Rule"). Phase I provided a comprehensive review of the statutory history of the Stark Law and implemented: (1) the general statutory prohibition on referrals; (2) statutory and regulatory definitions, including definitions of direct and indirect ownership or investment interests, direct and indirect compensation arrangements, and group practice; (3) the statutory exceptions for ownership and compensation arrangements, including in-office ancillary services; (4) new regulatory exceptions for ownership and compensation arrangements, such as academic medical centers; and (5) new regulatory compensation exceptions, for example, for fair market value and indirect compensation arrangements.

The Phase II Final Rule provides responses to comments and changes to Phase I, implements the remaining statutory exceptions, and promulgates new regulatory definitions and exceptions.

For those already facing withdrawal symptoms at the prospect of not reviewing any more Stark Law regulations, relief is at hand. There will be a Phase III Final Rule that will implement the Stark Law for referrals for Medicaid covered DHS services and provide comments and responses to the Phase II Final Rule.

Because this Phase II Final Rule provides comments and responses to Phase I and implements the remaining sections of the Stark Law not covered by Phase I, CMS encourages the public to read the two rules "together as a unified whole." Similarly, we encourage readers to read this Summary and Analysis together with our similar document for Phase I published in *BNA's Health*

*Care Fraud Report*, Vol. 5, No. 2, Analysis & Perspective, (January 24, 2001) (5 HFRA 87, 1/24/01).

## II. HIGHLIGHTS OF PHASE II

The Phase II Final Rule builds on CMS's attempt in Phase I to reduce the regulatory burdens imposed on providers and to provide increased flexibility for providers when structuring arrangements. We summarize here some of the more significant changes contained in the Phase II Final Rule.

■ CMS created eight new regulatory exceptions not tied to any of the exceptions based in the statute:

- Arrangements that have temporarily fallen out of compliance with a Stark Law exception due to events beyond the provider's control;
- Intra-family referrals in rural areas;
- Charitable donations by physicians;
- Referral services;
- Obstetrical and malpractice insurance subsidies;
- Professional courtesy;
- Retention payments; and
- Community-wide health information systems.

■ As a result of enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), CMS indicated that it would revisit the definition of "outpatient prescription drug" in a future rule-making and stated that it was interested in receiving comments regarding potential approaches for expanding the definition to reflect the MMA's definition of "covered Part D drug."

■ CMS attempted to dissipate confusion regarding the interplay of the indirect compensation definition and time- or unit-based compensation arrangements by making clear that even if a time- or unit-based arrangement meets the special rules for such arrangements, the arrangement is nevertheless an indirect compensation arrangement that must meet an exception.

■ CMS took significant steps toward minimizing the differences in the various rules applicable to physician compensation arrangements and modifies these rules so as to more accurately reflect industry practices.

■ CMS expanded the definition of fair market value to include a provision deeming hourly compensation for a physician's personal services to be fair market value if the hourly payment is established using either of two specified methodologies.

■ In the wake of a great deal of controversy regarding CMS's interpretation of the term "set in advance" in Phase I, CMS modified this definition to permit certain percentage compensation arrangements.

■ CMS clarified the circumstances by which the exception for group practice profit shares and productivity bonuses apply.

■ DHS entities can only direct referrals from employed physicians, and CMS further narrowed the circumstances in which directed referrals are permitted.

■ For purposes of the in-office ancillary service exception, CMS introduced a clearer, more flexible test for determining whether services are furnished in the "same building," and, further, created three new alternative tests that are available to solo practitioners as well as group practices. All three tests require the office to be open for a specified number of hours each week

with the referring physician regularly practicing medicine at the site.

■ Under the Academic Medical Centers (“AMC”) exception –

- Affiliated medical schools need not be part of the AMC if the teaching hospital qualifies as an “accredited academic hospital.”
- CMS liberalized the rules for the teaching hospital to meet the requirements that fifty percent (50%) of the medical staff be faculty, with fifty percent (50%) of the admissions coming from faculty.
- CMS clarified that while voluntary and courtesy faculty may be counted for the purposes of complying with these two 50% rules, payments under this exception only apply to physicians employed by a component of the AMC, and therefore payments to voluntary and courtesy faculty must comply with another exception.
- CMS created deeming rules to determine compliance with the requirement that the referring physician devote substantial time to academic services or teaching.
- CMS eliminated the requirement that faculty practice plans be tax-exempt.
- CMS liberalized the requirements to document the affiliations among the components of the AMC.

■ Phase II implements the moratorium for ownership of specialty hospitals adopted in the MMA.

■ CMS significantly eased the requirements for structuring arrangements to fit within the space and equipment rental exceptions. The following are now permitted:

- Termination without cause provisions within one-year lease terms
- Month-to-month holdovers for up to six months
- Subleases; and
- Capital leases.
- CMS substantially modified the Stark Law exception for physician recruitment arrangements.
  - Recruitment payments from federally qualified health centers (“FQHC”) are now permitted;
  - Hospital residents and new physicians need not relocate in order to qualify for the exception;
  - Indirect payments to medical groups are permitted, but under tight restrictions, for example, requiring both the group and recruited physician to sign the agreement and *not permitting*:
    - A group’s costs under an income guarantee to be allocated to the recruited physician for amounts above the group’s “actual incremental costs;” and
    - The group to impose additional requirements on the recruited physician, such as a non-compete clause.
    - These requirements where payments flow to the existing medical practice will likely require a significant number of existing physician recruitment arrangements to be renegotiated.
- As noted above, the Final Rule creates a new exception for retention payments to physicians practicing in:
  - Health practitioner shortage areas (“HPSA”); and
  - Areas of “demonstrated need” as determined on a case-by-case basis through an advisory opinion.

This advisory opinion process is the first indication by CMS that it will allow this process to be used like the HHS Office of Inspector General’s (“OIG”) advisory

opinion program to permit arrangements determined to be of low risk of abuse and either innocuous or beneficial, but not otherwise permitted by the statute or regulation. With CMS soon to be arbitrating on community need for services, this suggests the federal health planning program may be rising again like the Phoenix, after being presumed long ago dead and buried since the early 1980s.

■ CMS eased the reporting requirements imposed on providers with a reportable financial relationship and indicated that it does not intend to issue reporting forms.

■ CMS clarified that under the Stark Law physicians are not liable for payment recoupments for claims submitted in violation of the statute, but are liable only for civil monetary penalties (“CMPs”) and only where the government can prove the physicians acted with knowledge of the violation.

■ Regarding the relationship between the Anti-Kickback Statute and its safe harbors to the Stark Law

- CMS maintains its position that the two statutes are distinct, requiring a separate analysis to determine compliance with each.
- CMS requires compliance with the Anti-Kickback Statute as a condition for qualifying under certain Stark exceptions.
- CMS creates two new regulatory Stark exceptions based exclusively on complying with an OIG Anti-Kickback safe harbor.

### III. COMMENTS AND CHANGES TO GENERAL PROHIBITION AND KEY STATUTORY TERMS FROM PHASE I

#### A. Introduction

Overall, CMS did not substantively alter the general prohibition in Phase II, but rather used individual exceptions to address commenters’ specific concerns as to its scope. Most of the changes to the general prohibition are in the nature of fine-tuning, such as CMS’s clarification of the term “entity,” as described below. The one exception to this is the broad new exception for temporary non-compliance. This so-called exception should actually be considered a change in the scope of the general prohibition, rather than its own discreet exception, because it applies to nearly all of the other exceptions in the Final Rule.

#### B. Temporary Non-Compliance Exception

In response to commenters’ requests for a “grace period” to accommodate temporary non-compliance with the Stark Law, Phase II creates a regulatory exception to the general referral prohibition in Section 411.353 for entities that temporarily fall out of compliance with the statute due to events beyond their control. CMS characterized this new exception as one of the most sought after, useful, and industry-friendly modifications within Phase II. This exception applies when a change in circumstance places an entity or a referral outside the protection of an exception that it previously met, provided that it formerly complied with the exception for at least 180 days. After the event that results in noncompliance, referrals that are otherwise prohibited may continue to be ordered, submitted, and paid for ninety days.

For instance, if a provider’s geographic area is reclassified from rural to non-rural, the rural provider owner-

ship exception will continue for ninety days, giving the entity time to restructure its financial arrangement or take other measures so as not to disrupt the continuity of patient care. CMS intends for this exception to be used sparingly and, at most, not more than once every three years per entity with respect to referrals from a particular physician. This provision does not apply when an entity falls out of compliance with the non-monetary compensation and medical staff incidental benefits exceptions, because these exceptions are renewed annually.

### C. Referral

Under the Stark Law, a referral is defined as a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation or establishment of a plan of care. In the Phase I Final Rule, CMS concluded that the term “referral” excludes services personally performed by the referring physician, and also solicited comments regarding whether the definition of “referral” should exclude services that are performed “incident to” a physician’s personally performed services or that are performed by a physician’s employees.

Although a number of commenters supported the exclusion of such services from the definition of “referral,” CMS chose to adhere to its original determination that “incident to” services performed by others, and services performed by physicians’ employees, are referrals for purposes of the Stark Law.

The definition of “referral” includes DHS provided in accordance with a “consultation” with another physician, including DHS performed or supervised by the consulting physician or any DHS ordered by the consulting physician. However, certain requests pursuant to a “consultation” by pathologists, radiologists and radiation oncologists are statutorily excluded from the definition of “referral.”

To accommodate concerns raised by consulting physicians in group practices and by radiation oncologists who furnish services that are ancillary and integral to radiation therapy services, the Phase II Final Rule modifies the criteria adopted in Phase I for identifying a “consultation” for purposes of the Stark Law. Accordingly, the Phase II Final Rule allows DHS to be supervised by a pathologist, radiologist, or radiation oncologist in the same group practice as the consulting pathologist, radiologist, or radiation oncologist, and expands the term “radiation therapy” to include necessary and integral DHS performed as part of radiation therapy treatment.

### D. Entity

To fall within the scope of the Stark Law, a referral must be to an “entity” furnishing DHS. CMS clarified in Phase II that an “entity” is the party to which CMS makes payment for the DHS, either directly, upon assignment on the patient’s behalf, or upon reassignment pursuant to CMS’s reassignment rules. As in Phase I, an “entity” does not include the referring physician himself or herself, but does include his or her medical practice.

## IV. COMMENTS AND CHANGES TO PHASE I DEFINITIONS OF DESIGNATED HEALTH SERVICES

### A. Listed Designated Health Services

The Stark Law lists the following DHS:

1. Clinical laboratory services;
2. Physical therapy, occupational therapy, and speech-language pathology services;
3. Radiology and certain other imaging services, including ultrasound;
4. Radiation therapy services and supplies;
5. Durable medical equipment and supplies;
6. Parenteral and enteral nutrients, equipment, and supplies;
7. Prosthetics, orthotics, and prosthetic devices and supplies;
8. Home health services;
9. Outpatient prescription drugs; and
10. Inpatient and outpatient hospital services.

Because some of these DHS are either relatively straightforward or contain issues of interest to only a small audience, we confine our discussion to only a few of these DHS, including those DHS that have been substantially modified from the Phase I Final Rule.

### B. General Principles

In the Phase I Final Rule, CMS took a new approach by defining the entire scope of a number of DHS according to the Current Procedural Terminology (“CPT”) and HCFA Common Procedure Coding System (“HCPCS”) codes that are commonly associated with those DHS and are familiar to the provider community. Those DHS that are defined by CPT and HCPCS codes are: clinical laboratory services, physical therapy, occupational therapy, and speech-language pathology services, radiology and certain other imaging services, and radiation therapy services and supplies.

The remaining DHS are not amenable to definition through codes. Certain DHS definitions, such as the definition of “radiology and certain other imaging services,” specifically include both the professional and technical components of a service. Other DHS definitions, such as inpatient and outpatient hospital services, specifically exclude the professional component, while services such as physical and occupational therapy are inherently professional in nature.

### C. Radiology and Certain Other Imaging Services

The Phase II Final Rule modifies the definition of “radiology and certain other imaging services” to make clear that radiology services, which are performed immediately after a procedure in order to confirm the placement of an item inserted during the procedure, are not DHS. Several commenters advocated for special exceptions for certain radiological procedures, claiming either that the specified procedures were subject to little or no overutilization or abuse, or that beneficiaries would benefit from the exception; however, CMS declined the opportunity to create any new exceptions. CMS further noted that the change in the definition of “referral,” and the in-office ancillary services and physician services exceptions sufficiently address many of the commenters’ concerns.

In response to a comment that CMS should consider nuclear medicine to be a DHS because excluding it increases the risk of program abuse, CMS stated that Phase II makes no changes to the treatment of nuclear medicine procedures under the DHS definitions. However, CMS also stated that it is mindful of the comment-

er's concerns and will continue to consider the application of the Stark Law to nuclear medicine procedures.

#### **D. Outpatient Prescription Drugs**

In the Phase II Final Rule, CMS notes that due to enactment of the MMA, as of January 1, 2006, many additional outpatient prescription drugs will be covered under Medicare Part D, and indicated that it will revisit the definition of "outpatient prescription drugs" in a future rulemaking. CMS stated that it is interested in receiving comments regarding potential approaches to expanding this definition to reflect the definition of "covered Part D drug" in the MMA.

CMS also clarified that drugs administered in the physician office setting fall within the definition of "outpatient prescription drugs," and noted that, typically, such drugs will either fall within the in-office ancillary services exception, or will not constitute a referral when administered personally by the referring physician.

#### **E. Inpatient and Outpatient Hospital Services**

Referencing the "unique legislative history" surrounding the application of the Stark Law to lithotripsy, CMS states in Phase II that, while it is not revising the regulatory definition, it no longer considers lithotripsy an "inpatient or outpatient service" for purposes of the Stark Law. This change follows an opinion of the United States District Court for the District of Columbia, in which the court held that the legislative history of the Stark Law demonstrated that Congress never regarded lithotripsy as part of the self-referral problem and has consistently acted to exclude it from the regulation of self-referrals. See *Am. Lithotripsy Soc'y and Urology Soc'y of Am. v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002).

CMS, however, noted that contractual arrangements between hospitals and physicians or physician practices regarding lithotripsy nevertheless constitute a "financial relationship" for purposes of the Stark Law. As such, these contractual arrangements must comply with an exception if the physician will refer Medicare patients to the hospital for services that otherwise fall within the definition of "inpatient or outpatient hospital services" or another DHS. This approach serves to undermine any gains that providers of lithotripsy thought they may have won based on the District Court's opinion because the lithotripsy contract still must satisfy one of the exceptions if the physicians refer any other patients to the hospital.

### **V. COMMENTS AND CHANGES TO PHASE I INDIRECT COMPENSATION DEFINITION AND EXCEPTION**

#### **A. Definitions of Indirect Compensation, Volume or Value and Other Business Generated**

In Phase I, CMS created a definition and parallel exception for indirect compensation. The definition contained a three-part test: (1) there is an unbroken chain of financial arrangements (either ownership or compensation) linking the referring physician to the entity furnishing DHS; (2) when focusing on the last financial arrangement in the chain that involves a direct payment to the physician, the *aggregate* compensation paid to the referring physician varies with, or otherwise takes into account the volume or value of referrals to, or business generated for the DHS entity; and (3) the DHS en-

tity has knowledge that the *aggregate* compensation varies in this manner.

In applying this test, Phase I also provided that unit-based compensation methodologies (such as "per click" fees) will be deemed not to take into account the "volume or value of referrals" or "other business generated between the parties" if the compensation is at fair market value and does not vary during the course of the compensation in any manner that takes into account referrals of DHS.

In the Phase II Final Rule, CMS noted that a number of people were confused about the scope of the indirect compensation definition and its relationship to the "volume or value" and "other business generated" standards and to the indirect compensation exception. Responding to such concerns, CMS explained that the basic definition of indirect compensation focuses on whether the *aggregate* compensation varies with or takes into account the volume or value of referrals. With respect to time-based or unit-of-service compensation, CMS believes that the aggregate compensation always takes into account the volume or value of referrals, and so an indirect compensation arrangement exists that would require compliance with one of the exceptions.

The problem raised by the commentators is that the special rules for time- or unit-based methodologies can be deemed not to take into account the "volume or value" of referrals or "other business generated" if certain standards are met, in which case an indirect compensation arrangement would not exist. The implications are that the arrangement in this example falls outside of the Stark Law and therefore the parties need not even comply with one of the exceptions. CMS clarified that this was not the intent and that the arrangement should be characterized as an indirect compensation arrangement that would need to meet an exception.

The fix is to make clear in the regulation text that even if a time- or unit-based arrangement meets the special rules, the arrangement is nevertheless an indirect compensation arrangement.

CMS makes no meaningful changes to the exception itself, meaning that under the Phase II Final Rule a fair market value indirect compensation arrangement is permitted if the compensation (not aggregate compensation) does not take into account the volume or value of referrals or business generated, and the other standards discussed above are met. It is important to note, however, that while some exceptions contain the standard requiring that the compensation must be set in advance (as discussed in Section VI.C), this does not include such a standard. In addition, these rules pertaining to time- or unit-based compensation relate to several other exceptions affecting physician compensation. See discussion in Section VI.

We note that while this approach clears up what seemed like a gaping loophole, we are not sure if CMS's approach has fully addressed the problem for non-fair market value fixed compensation arrangements. In the Preamble, CMS opined that such arrangements take into account the volume or value of referrals. However, a straightforward reading of the regulation would not necessarily lead to the same conclusion. In addition, CMS's approach still strikes us as so complicated that it will require providers to regularly seek legal counsel to work through the mechanics of these rules.

CMS received a number of comments regarding the implications of compensation arrangements with physician professional corporations (“PC”) for services of the physician shareholder. Specifically, commenters were concerned that such arrangements could constitute indirect compensation arrangements, at least in so far as they met the requirements of that definition. In response, CMS does clarify that the physician stands in the shoes of his or her PC if the physician is the sole owner, and therefore such arrangements appear to be direct compensation.

### **B. Exception for Indirect Compensation Arrangements**

If an arrangement constitutes an indirect compensation arrangement under the indirect compensation definition, the arrangement must satisfy the indirect compensation exception. This regulation-created exception generally requires that: (1) the compensation must be set at fair market value not taking into account the volume or value of referrals or business generated; (2) the arrangement must be a signed written agreement specifying the services covered; and (3) the compensation does not violate the Anti-Kickback Statute. See our discussion of the Stark Law’s relationship to the Anti-Kickback statute in Section XV below.

In Phase II, CMS remedied the problem that the Phase I Final Rule could be construed so that an indirect compensation arrangement meeting that exception could cure (or permit) an otherwise prohibited ownership arrangement that is at the beginning of the “unbroken string.” Such a result, of course, would directly contravene the express language and fundamental purpose of the Stark Law — to generally prohibit physicians from referring to DHS furnishing entities in which they have an ownership interest.

## **VI. COMMENTS AND CHANGES TO PHASE I EXCEPTIONS RELATED TO PHYSICIAN COMPENSATION**

### **A. Introduction**

There is no better example of the reach of the Stark Law than its regulation of physician compensation. These rules appear in a number of places throughout the Stark Law and the Phase I Rule, and in several places distinctions are made in the treatment of incentive compensation that in some cases are perplexing and in most cases merely lead to confusion. In the Phase II Final Rule, CMS takes additional, important steps toward minimizing the differences in the various rules applicable to physician compensation arrangements.

Although a number of differences still exist in the rules for physician compensation depending on whether the physician is an employee, member of a group practice or independent contractor, these differences have been narrowed and CMS makes efforts to simplify any analysis of a compensation arrangement by inserting into the Preamble a chart summarizing the various compensation rules. This CMS chart is attached as *Exhibit A*.

Despite CMS’s attempts at simplifying the requirements for those physician compensation arrangements that do not violate the Stark Law, legal practitioners providing advice on physician compensation arrangements must still review carefully the special rules on compensation, the individual exceptions for employees,

personal services, fair market value and academic medical centers as well as the rules for group practices and the definitions of fair market value and physician incentive plans.

In this section, we will summarize the key changes that CMS has made to these physician compensation requirements in Phase II.

### **B. Fair Market Value Definition and Exception**

The overarching principal running through most of the physician compensation rules is that the compensation must be consistent with fair market value. With the exception of one important addition discussed below, the definition of fair market value remains the same as was set forth in the Proposed Rule and Phase I.

Of note, while CMS has not changed the definition of fair market value to exclude space leases, that section of the Preamble takes the unusual position that the term “items and services” does not include space leases and therefore this exception is not available for such arrangements. While the practical effect of this interpretation may not be important, we note that CMS’s interpretation of this term is new and not consistent with the OIG’s definitions.

#### *1. Hourly Payment Exception*

Responding to requests to provide more bright line rules, CMS adds to the definition of fair market value a provision deeming hourly compensation for a physician’s personal services to be fair market value if the hourly payment is established using either of two specified methodologies. The first is tied to the average hourly rate for emergency room physician services in the relevant market, and the second is tied to the average compensation level for physicians in the same specialty area using established national physician compensation surveys that are listed in the rule itself. To fit within this deemed status, payment must be for the physician’s personal services and not for services performed by the physician’s employees, contractors or others. The Preamble makes clear that these are merely deeming rules, but not mandatory requirements.

#### *2. Commercially Reasonable*

Several of the compensation exceptions, including the Fair Market Value exception, require that an arrangement be “commercially reasonable.” Responding to concerns that CMS was injecting too much subjectivity into the term “commercially reasonable,” the Phase II Preamble notes that “an arrangement will be considered ‘commercially reasonable’ in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician. . . of similar scope and specialty even if there were no potential DHS referrals.”

### **C. Set In Advance**

#### *1. Percentage Based Compensation and Productivity Bonuses*

The Personal Services, Fair Market Value and Academic Medical Centers exceptions have been invaluable to physicians and those entities to which they refer, especially hospitals. All three exceptions require that the physician’s compensation be “set in advance.” Despite CMS’s efforts in the Phase I Final Rule to interpret the exceptions broadly and to avoid the “unintended disruption of common financial relationships,” the Phase I Final Rule generated a great deal of controversy with its interpretation of the “set in advance” requirement, es-

pecially as applied to percentage based compensation. The Phase I Final Rule added the following sentence to the Special Rules on Compensation:

Percentage compensation arrangements do not constitute compensation that is “set in advance” in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same services from the same purchasers.

Just prior to the January 2002 effective date of the Phase I Final Rule, CMS delayed the effective date of this percentage compensation provision set forth above. On three additional occasions, CMS further delayed the effective date of this provision. Finally, as part of the Phase II Final Rule, this controversial provision has been eliminated. CMS responded to the criticism voiced by physicians and the entities with whom they contract and agreed that its original position was “overly restrictive.” Now, under the Personal Services, Fair Market Value and Academic Medical Center exceptions, physicians can be paid a percent of revenues for personally performed services or receive a productivity bonus.

#### 2. *Specific Formula*

Physicians and the entities with which they have a compensation relationship have been given more leeway in structuring a compensation arrangement to meet the “set in advance” requirements. In addition to agreeing upon the aggregate compensation or time or unit based compensation, CMS will now permit a “specific formula” for calculating the compensation. So long as the specific formula is detailed, capable of being objectively verified and does not change over the course of the contract, it will be considered to be “set in advance.”

#### **D. Compensation to Physicians in a Group Practice**

As a result of the changes to the “set in advance” requirement, the rules for physician compensation resemble more closely the broad rules for productivity bonuses in the group practice setting with one key distinction. Consistent with the Stark Law, CMS clarified its intent in Phase I to permit physicians in group practices to be paid productivity bonuses based on services that are “incident to” the physician’s services. In the Phase II Final Rule, CMS modified the rules on profit shares and productivity bonuses to clarify that the product sharing and productivity bonus safe harbors serve as deeming provisions, not absolute requirements.

Additionally, CMS explained that the safe harbors apply if: 1) less than five percent (5%) of the group’s total revenues are derived from DHS; and 2) that portion of the share or bonus allocated to each individual physician constitutes less than five percent (5%) of his or her total compensation from the group practice.

#### **E. Compensation to Physician Employees**

##### 1. *Personally Performed Services*

Productivity bonuses to employees under the Bona Fide Employment exception are permitted so long as they are based on services personally performed by the physician. CMS refused to adopt the limitation in the Proposed Rule that would have excluded any productivity bonus based on a physician’s own referrals of DHS, even where personally performed. CMS reasoned that personally performed services are not referrals. As to referrals for services that are not personally performed services, such as supervision services, these payments

must meet the Fair Market Value exception. CMS is concerned that payments for supervision services “could mask improper cross referral or circumvention schemes.”

##### 2. *Leased employees*

The Phase I commenters continued to press for an expanded definition of the term employee to include leased employees as defined by state law. CMS reiterated its concern that incorporation of state law definitions of employment would be inconsistent with the statute which is based on the Internal Revenue Service (“IRS”) definition of employee. However, to the extent that a leased employee is a bona fide employee of the DHS entity under IRS rules, remuneration paid to that employee would be eligible under the Bona Fide Employment exception.

##### 3. *Directed Referrals*

In the Phase II Final Rule, CMS narrows the availability of the directed referral rule to provide that only physician compensation from a bona fide employer or under a managed care contract may be conditioned on the physician’s referrals to a particular provider or supplier. In addition to having this exception applying only to an employment or managed care arrangement, CMS adds the requirement that such directed referrals must relate solely to the physician’s services under his or her employment or contract and must be reasonably necessary to “effectuate the legitimate business purposes of the compensation relationship.” Referrals cannot be required, however, when the patient expresses a different choice, the patient’s insurer determines a different provider or when the referral, in the judgment of the physician, is not in the best medical interest of the patient.

All of these changes are a logical attempt to close what appeared to be a large loophole from Phase I that permitted a direct link of payment and referrals that raised serious questions of Anti-Kickback Statute violations. In Section XV below we provide a more complete discussion of the relationship between the Anti-Kickback Statute and the Stark Law.

#### **F. Compensation to Physician Independent Contractors**

For physicians who are not employees or part of a group practice, the Personal Services exception is one of the most commonly used. CMS notes that this exception is the applicable exception for most foundation-model physician practices. The Phase II changes to the “set in advance” requirements discussed above and to the fair market value definition for hourly payments for physicians will give physicians and providers more flexibility when crafting an arrangement to fit within the Personal Services exception.

##### 1. *Termination*

In addition, CMS grants providers more leeway with regard to termination of contracts prior to the end of the required one-year term. Similar to what it did in the Phase I Final Rule with the Fair Market Value exception, CMS adds the following to the “one year” requirement: “To meet this requirement, if an arrangement is terminated during the term with *or without* cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement” (emphasis added).

##### 2. *Master List of Contracts*

The Proposed Rule required that the personal services contract cover all of the services to be furnished

by the physician and that all separate arrangements between the entity and the physician (and the entity and any family members) “incorporate each other by reference.” Objections to this requirement were raised citing concerns about the undue administrative burden that this would pose on providers with a high volume of physician contracts.

Agreeing with commentators, CMS relaxed the Personal Services exception requirements under the Phase II Final Rule. The Personal Service exception now allows a contract to meet the requirement that it covers all the services either through incorporation by reference, or alternatively, through cross-referencing a master list of contracts. This master list of contracts must be maintained and updated centrally and be available for review by the Secretary upon request.

### 3. “Furnishing Services”

CMS adds another clarification to the Personal Services exception that goes a long way towards acknowledging the practical realities of a physician’s practice. Under the Personal Services exception, physicians can “furnish” services through *locum tenens* and a wholly-owned entity, in addition to furnishing services through employees.

### 4. Physician Incentive Plan Exception

The requirement in the Personal Services exception that the compensation not take into account the volume or value of any referrals or other business generated between the parties does not apply to a physician incentive plan (“PIP”). To meet the PIP exception, no payments can be made as an inducement to reduce or limit medically necessary services. In addition, where a physician or physician group is at substantial financial risk, the PIP must comply with the general PIP regulations promulgated by CMS. The Phase II Final Rule expands the definition of a PIP to include arrangements involving downstream subcontractors of the entity.

## G. Compensation to Physicians in Academic Medical Centers

One of the principal nagging issues facing CMS from Phase I was how to deal with the “set in advance” rules regarding percentage-based compensation arrangements, especially in the context of faculty practice plans. The changes discussed in Section VI.B and VI.D above relate equally to AMCs, because the AMC exception requires that compensation be fair market value and set in advance. Importantly, CMS did clarify that when an AMC is examining salary comparables to determine fair market value, it is free to look at salary information for either academic physicians or for private practice physicians. This change removes any lingering questions regarding whether an AMC is allowed to match a private practice salary offer in order to retain a top-level physician.

In addition, this exception requires that the compensation not take into account the volume or value of referrals or business generated by the referring physician. Finally, CMS clarified in Phase II that any monies paid by an AMC to a physician for research under this exception may also be used for teaching and must be consistent with the grant purposes, but may not be used for indigent care or community service. In all likelihood, other exceptions would be available for such expenditures. Our discussion of other provisions of the AMC exception is found at Section IX below.

## VII. COMMENTS AND CHANGES TO PHASE I DEFINITION OF GROUP PRACTICE AND IN-OFFICE ANCILLARY SERVICES EXCEPTION

### A. Group Practice Definition

The term “group practice” is relevant for compliance with various Stark Law exceptions, particularly the In-Office Ancillary Services exception. According to CMS, most comments on the Phase I Final Rule were favorable and commended the definition’s flexibility. The most significant changes to the definition in Phase II concern clarification of the single legal entity requirement’s applicability to multi-state entities, expansion of the grace period for meeting the “substantially all” test when a new physician relocates his or her practice, and the deletion of one prong of the unified business test. Please note that our discussion of the requirements for compensating physicians in a group is found in Section VI.D above.

#### 1. Single Legal Entity

A group practice must consist of a single legal entity formed primarily for the purpose of being a physician group practice. CMS clarified that an entity with any substantial purpose other than operating as a physician practice, such as running a hospital, cannot meet this standard. CMS noted that a hospital can legally organize, own, or operate a group practice established as a separate legal entity, but that the hospital itself cannot qualify as a group practice.

CMS also amended the regulation to allow a physician practice consisting of multiple legal entities operating in more than one state to qualify as a single legal entity, but only if certain conditions are met. Finally, CMS continued to caution that a group practice owned by a functioning medical group cannot meet the single legal entity requirement.

#### 2. Members of the Group

The term “members of the group” is a component of various group practice prerequisites, one of which requires a group practice to have at least two physicians who are “members of the group.” Although the Phase I Final Rule prohibited independent contractors and leased employees from qualifying as such, CMS modified the definition to reflect that a leased employee may be considered a member of group if he or she is a bona fide employee under IRS rules. In addition, in the Phase II Final Rule, CMS clarified that part-time employed physicians also may qualify as members of the group for purposes of the two or more physicians requirement, but CMS refused to reconsider its previous decision to exclude independent contractors.

#### 3. The “Full Range of Services” Test

CMS clarified that donating patient care at free clinics should not prevent a physician practice from meeting the “full range of services” test, which requires each member of the group to furnish substantially all of the full range of patient services that the physician routinely furnishes through the joint use of shared office space, facilities, equipment, and personnel. According to CMS, this test does not require “absolute identity” of services. If the donated services are within the same scope of services that are provided as part of the group, then the group still should meet the full range of services test as well as the substantially all test, which is discussed in more detail below. A group practice may structure the donated services so that they are billed

through the group even though the group need not actually send or collect on the bill.

#### 4. The "Substantially All" Test

CMS made no significant changes to the basic requirement that "substantially all" (i.e., seventy-five percent (75%)) of the patient care services provided by members of the group must be furnished through the group and billed under the group's billing number, and payments must be treated as receipts of the group. However, CMS expanded the circumstances under which it will allow a grace period for a physician practice to come into compliance with the substantially all requirement. In response to comments pointing out that the addition of a new physician can jeopardize group practice status because of delays in obtaining Medicare billing numbers, CMS added a new twelve-month grace period to accommodate a group practice when a new physician relocating his or her practice joins the group.

CMS clarified that group practices with members who provide substantial patient care services at AMCs must still meet the substantially all test. To the extent such groups have difficulty doing so, they may arrange to bill the care through the group and treat amounts received as group receipts. CMS cautioned that although a medical school group practice may qualify for the in-office ancillary services exception, it may use the exception to protect referrals within the group practice, but not referrals to other components of the AMC.

#### 5. The Unified Business Test

The Phase II Final Rule eliminates one of the three prongs of the unified business test, and, as a result, a group practice is no longer required to conduct centralized utilization review to qualify as a unified business. In response to a comment concerning the centralized decision-making aspect of the test, CMS stated that substantial group level management and operation must occur. In other words, those responsible for maintaining control over the group's assets and liabilities cannot just "rubber stamp" decisions based on the various cost centers or locations.

### B. In-Office Ancillary Services Exception

According to CMS, the comments received on the In-Office Ancillary Services exception were "overwhelmingly positive," but a number of commenters raised concerns about the building requirements. In response, CMS simplified the "same building" and "centralized building" tests. Other changes to the In-Office Ancillary Services exception are relatively minor and not discussed here.

Generally, in-office ancillary services must be furnished in either the "same building" where the referring physician or his or her group practice provides professional services or in a "centralized building" used to provide off-site DHS. According to CMS, this requirement helps to ensure that DHS qualifying for the exception are truly ancillary and therefore are not provided as part of a separate business enterprise. CMS made no substantive changes to the definition of "centralized building," and also rejects comments seeking a more flexible definition of "same building." Only one minor modification is made to the definition of "same building" to establish that loading docks are not part of the building to ensure that mobile vans or other facilities do not fall under the definition.

The most significant change to the building requirement is CMS's introduction of three new alternative

tests, which are available to both solo practitioners as well as group practices, for determining whether services are furnished in the "same building." CMS believes that these tests are more flexible, permitting many arrangements to qualify now that previously did not, as well as continuing to allow virtually all arrangements that previously complied with the Phase I test. However, CMS noted that the few arrangements that previously qualified under Phase I, but do not qualify now, must be restructured or unwound before the effective date of Phase II.

- The first new test generally describes a building where a physician or group's primary place of practice is located. Under this test, the office must be normally open at least thirty-five hours per week to patients, and it must be used regularly by the referring physician or by one or more members of his or her group practice to practice medicine and to furnish physician services at least thirty hours per week. Additionally, "some" of the thirty hours of physician services must be unrelated to DHS.

- The second test generally describes a building where a referring physician practices at least one day per week and at which patients usually receive services from the referring physician or a member of his or her group practice. This test is met if the office is normally open at least eight hours per week to patients, and is used regularly by the referring physician to practice medicine and to furnish physician services at least six hours per week. Again, the six hours per week must consist of "some" physician services unrelated to the furnishing of DHS.

- Finally, under the third new test, the office must normally be open at least eight hours per week to patients, and it must be used regularly by the referring physician or by one or more members of his or her group practice to practice medicine and to furnish physician services at least six hours per week. The six hours of services per week must consist of "some" non-DHS physician services. This test also requires that the referring physician be present and order the DHS during a patient visit in the office, or the referring physician or a member of his or her group must be present when the DHS is provided on the premises.

All three tests require the office to be open for a specified number of hours each week with the referring physician regularly practicing medicine at the site. CMS noted that these tests can still be satisfied even if there are occasional weeks when the offices are open for fewer hours (such as during a vacation), or the offices have open appointments, cancellations, or other occasional gaps in the furnishing of services. CMS also declined to set a particular threshold for the requirement that "some" of the physician services must be unrelated to the furnishing or ordering of DHS. Rather, CMS stated that it will interpret "some" according to its "common sense meaning."

Finally, under Phase I there is a special rule for physicians who primarily treat patients in their private homes to allow these physicians, who do not actually practice in a building, to meet the exception's building requirement. These physicians can meet the same building test if the DHS are provided in a private home contemporaneously with a physician service that is not DHS. The rule does not apply to services provided in a nursing, long term care, or other facility or institution, but CMS amended this rule to cover services provided

in a private home in an independent living or assisted living facility. Such facilities, however cannot have a common examination room.

## VIII. COMMENTS AND CHANGES TO PHASE I MANAGED CARE PREPAID PLANS AND RISK-SHARING EXCEPTIONS

In the Phase I Final Rule CMS deferred its treatment of Medicaid managed care plans until Phase II. Rather than create a separate exception for Medicaid prepaid plans as discussed in the Proposed Rule, CMS instead decided to amend the existing exception for prepaid plans to cover referrals of enrollees in Medicaid managed care plans similar to the Medicare managed care plans already included in the exception.

The regulatory risk-sharing exception, which was established in Phase I, applies to compensation paid pursuant to a risk-sharing arrangement for services provided to enrollees of a health plan. CMS clarified that this exception is intended to cover all risk-sharing compensation paid to physicians by any downstream entity, provided that the terms of the exception are met. CMS declined to define the term “managed care organization” to maintain maximum flexibility and to expand the exception to include referrals to entities owned by a managed care organization even if the patients are not enrollees.

## IX. COMMENTS AND CHANGES TO PHASE I EXCEPTION FOR ACADEMIC MEDICAL CENTERS

CMS’s Phase I AMC exception specified requirements for the various components of an AMC and its relationship with faculty physicians and other referring physicians, all of which we will discuss in this section. The AMC exception also contains requirements for the compensation paid to the referring physician, which are discussed separately in Sections V and VI above.

### A. Teaching Hospital

The Phase II Final Rule no longer requires an accredited medical school to be a component of the AMC, but permits the teaching hospital to be the only component of the AMC to provide teaching and education if it meets the new requirements of an “accredited academic hospital” (“AAH”). Such hospitals must sponsor (alone or in conjunction with other parts of the AMC) four approved medical education programs. The teaching hospital must also meet certain faculty requirements. Although CMS did not change the requirement that a majority of the hospital’s medical staff must be faculty physicians and a majority of the admissions must come from faculty physicians, it made the following accommodations to facilitate compliance with these two fifty percent (50%) rules:

- The faculty physician may be on the faculty of the medical school or one or more of the educational programs of the AAH. This means that both the faculty of the medical school and the AAH may be counted.
- Any faculty may be counted, whether or not the physician is an employee, meaning that courtesy or volunteer faculty can be included in the count.
- Residents and non-physician professionals should not be counted.

### B. Referring Physician

CMS clarified that the AMC exception covers payments to referring physicians who meet the require-

ments of the exception. While the referring physician must be a faculty member as discussed above, he or she must *also* be a bona fide employee (at least on a substantial part-time basis) of a component of the AMC. Thus, while volunteer faculty will be counted for the purposes of determining whether the hospital qualifies as a component of the AMC, payments to such physicians are not permitted under this exception, but must qualify under another exception.

CMS also explained that in determining whether the referring physician provides *substantial* academic services or clinical teaching, the parties may use any “reasonable and consistent” method for calculating these services. CMS also created a deeming standard for compliance with this AMC service requirement: twenty hours per week or at least twenty percent (20%) of the physician’s professional time. CMS made clear that this standard was not a formal requirement, and that failure to meet either of these standards did not preclude the parties from showing in other ways that the referring physician provided substantial academic services or clinical teaching services.

### C. Faculty Practice Plans

In addition to a teaching hospital, an AMC must have one or more faculty practice plans. In responding to comments, CMS eliminated the requirement that the faculty practice plan must be tax-exempt.

### D. Other Components and Requirements of an AMC

CMS clarified that the supporting documentation necessary to show the affiliation between components of the AMC need not be in a written agreement, but may be in a series of documents. The Phase II Preamble states that the evidence of an affiliation may be “a clearly established course of conduct that is appropriately documented.” CMS also explained that an AMC may consist of a single legal entity, in which case the documentation may be financial reports documenting the transfer of funds. Finally, a non-profit support organization may be included as a component of an AMC, thereby protecting the transfers of funds from that entity so long as the primary purpose of the support organization is supporting the teaching mission of the AMC.

## X. COMMENTS AND CHANGES TO PHASE I EXCEPTIONS RELATED TO BOTH OWNERSHIP AND COMPENSATION, INCLUDING NEW PHASE II EXCEPTION

### A. Introduction

In addition to the ownership and compensation exceptions discussed above, the Phase II Final Rule also includes several exceptions for arrangements that CMS has determined pose a minimal risk of abuse. CMS promulgated seven such exceptions at Phase I which relate to both ownership and compensation arrangements. In Phase II, CMS left three of these exceptions largely undisturbed, namely, those relating to: (1) ambulatory surgery center (“ASC”) implants; (2) preventive screening, vaccinations, and immunizations; and (3) eyeglasses or contacts following cataract surgery. The only modification to the preventive screening exception is the deletion of the fee schedule requirement for reimbursement. As discussed below, CMS also deleted one of these seven exceptions, amended one, and added one.

## B. EPO and Other Dialysis-Related Outpatient Prescription Drugs

Phase I established a list of dialysis-related treatments, identified by CPT/HCPCS codes, that qualify for an exception. CMS created this exception based on its determination that these end-stage renal disease (“ESRD”) services are less vulnerable to abuse than other financial arrangements. Of note, only ESRD facilities can qualify under this exception.

Phase II expands this list to include certain other drugs, including certain outpatient drugs furnished by the ESRD facility that do not dialyze, but that promote the efficacy of the dialysis treatment, such as thrombolytics for de-clotting catheters. CMS declined commenters’ requests to add other drugs to the list where it determined the drug was already included in the Medicare composite rate for their accompanying procedures, and therefore do not constitute DHS.

## C. “Composite Rate” Exception Deleted At Phase II

In the 1995 Final Rule, CMS specifically exempted from the statute’s prohibitions certain clinical laboratory services performed as part of a larger service billed to Medicare under a composite rate, such as pathology tests accompanying surgery in an ASC, a hospice, or an ESRD facility. CMS retained this “composite rate” exception in the Phase I Final Rule, which also added separate exceptions for specific DHS often performed in conjunction with composite rate services, such as ASC implants and inpatient ESRD prescription drugs. Phase I also amended the definition of DHS to exclude composite rate services, except where explicitly mentioned by the Stark Law. In view of both the separate exceptions and the revised DHS definition, CMS agreed with commenters that the composite rate exception is obsolete and only serves to create confusion. Therefore, CMS deleted the composite rate exception.

## D. Intra-Family Referrals in a Rural Area

Phase II contains a new regulatory exception under which a physician can refer a patient living in a rural area to an entity in which his or her immediate family member has either an ownership or compensation interest. This exception applies only if there is no other entity within 25 miles of the patient’s home, or otherwise available to furnish DHS in a timely manner based on the patient’s condition.

Theoretically, both the referring physician and the entity could be located in an urban area and still avail themselves of the exception. The Preamble emphasizes that unlike other location-based exceptions, this exception is based on where the DHS services are provided, rather than the location of either the referring physician or the DHS entity. This provision has the unique effect of excepting some, but not all, of the patients referred to an entity by a particular physician.

For example, a physician may have both patients who live within 25 miles of another DHS, and patients who do not, but only the latter can be referred to the DHS connected to the family member. Accordingly, providers who utilize this exception should be aware of which patients qualify for the exception and which do not. Those providers should also track their patients’ rural or urban geographical classification, and stay abreast of

any changes to urban or rural boundaries as defined by the regulations.<sup>2</sup>

## XI. OWNERSHIP AND INVESTMENT INTEREST EXCEPTIONS (PHASE II)

### A. Introduction

The Phase II Final Rule addresses the statutory exceptions relevant to ownership and investment interests for the first time. Some of these exceptions, for example for ownership or hospitals in Puerto Rico and rural areas, track virtually identically the related statutory exceptions, and will not be discussed here. The other exceptions for publicly traded securities, mutual funds and hospital ownership have been modified and we discuss these changes. See also Section X.D above for our discussion of the Intra-Family exception applicable to rural areas.

### B. Publicly Traded Securities and Mutual Funds

In identifying whether an ownership interest meets the exception for publicly traded securities, CMS applies the following three-part test. First, the securities owned by the physician or his or her family member “must be securities that may be purchased on terms generally available to the public.” Such investments include shares or bonds, debentures, notes, or other debt instruments. In the Phase II Final Rule, CMS interpreted this provision to mean the ownership interest must be in securities that are “generally available to the public *at the time of the DHS referral.*”

In contrast, in the Proposed Rule, CMS interpreted this provision to mean that, *at the time the physician obtained the ownership interest*, the security interest could have been purchased on the open market. For example, under Phase II, securities acquired by a referring physician or his or her family member prior to a public offering will fit within the exception, assuming other conditions in the exception are satisfied, if they are available to the public at the time of any DHS referral. Further, the Preamble to the Phase II Final Rule notes that CMS will not consider stock options received as compensation to be ownership or investment interests until the time of exercise.

Second, the securities owned by physicians must either be: (1) listed for trading with an exchange whose quotes are published daily, such as NYSE or ASE; or (2) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

Third, an investment does not constitute a prohibited financial interest as long as such securities are “in a corporation that had shareholder equity exceeding \$75 million at the end of the corporation’s most recent fiscal year or on average during the previous three fiscal years.”

Similarly, the Phase II Final Rule excepts from the statute’s ownership prohibitions investments in mutual funds, as defined in section 851(a) of the Internal Revenue Code, that have total assets exceeding \$75 million at the end of the most recent fiscal year, or on average

<sup>2</sup> At this time, it is unclear whether patients living in so-called “micropolitan” statistical areas would be considered rural area patients for the purposes of this exception. CMS states that this issue will be resolved in a forthcoming regulation not related to the Stark Law.

during the previous three (3) fiscal years. Again, the purpose of this requirement is to diminish the financial incentives for physicians to refer to DHS entities. CMS views the \$75 million benchmark as a threshold level at which any tie between a physician's referrals and investment returns is attenuated.

### **C. Hospital Ownership**

For DHS provided by a hospital, a physician's ownership interest in that hospital will not be deemed a financial relationship so long as (1) the referring physician is authorized to perform services at the hospital; (2) the hospital is not a specialty hospital for the eighteen-month period beginning December 8, 2003; and (3) the ownership interest is in the hospital as a whole, not merely a department or subsection.

Specialty hospitals include hospitals primarily or exclusively engaged in the care and treatment of patients with a cardiac condition, orthopedic condition or patients receiving a surgical procedure. A physician may still refer to a specialty hospital in which he or she has an ownership interest if that hospital was "under development" as of November 18, 2003, as determined by section 507 of the MMA, or alternatively, by an advisory opinion from CMS. Such referrals are also permitted to specialty hospitals that were in operation as of November 18, 2003 so long as the hospitals do not: (1) add more physician investors; (2) furnish additional specialized services; or (3) add more beds, other than to the main campus of the hospital, and if so, not by more than five beds or fifty percent (50%) of the number of beds as of November 18, 2003. This specialty hospital moratorium also applies to ownership of such hospitals in rural areas that would otherwise be permitted under the rural exception.

Previously, CMS interpreted "provided by the hospital" to mean that the services have been provided by a "hospital" under Medicare's conditions of participation, and not by a hospital-owned entity, such as a skilled nursing facility or home health agency. Additionally, CMS had explained that a physician can maintain an ownership or investment interest in a hospital through holding an interest in an organization that owns a chain of hospitals, such as a health system, because the statute does not require that the physician have a direct interest in the hospital. Despite some objection, CMS adheres to these interpretations in Phase II.

## **XII. STATUTORY COMPENSATION EXCEPTIONS (PHASE II)**

The Phase II Final Rule addresses the statutory compensation exceptions for the first time. We have already discussed the statutory compensation exceptions for employment and personal services arrangements in Sections VI.E and F above.

### **A. Rental of Office Space and Equipment**

Pursuant to the Stark Law's statutory exceptions, lease arrangements for office space and equipment will not constitute a compensation arrangement provided certain conditions are met. The Phase II Final Rule significantly eases the requirements for structuring an arrangement to fit within the rental of office space and equipment exception.

#### *1. Provisions Applicable to Space and Equipment*

CMS adopted commenters' suggestion that the one-year term rule should include lease or rental agree-

ments allowing termination with or without cause, provided that the parties do not enter into a new agreement during the original term. In the Proposed Rule, CMS had proposed interpreting the one-year term requirement as permitting only termination with cause. Agreeing with commenters that termination without cause provisions are not likely to increase the risk of abuse when the parties are precluded from entering into a new agreement within the original lease or rental term, and also must structure any subsequent agreement to fit within an exception, CMS modified the regulations to permit lease or rental agreements containing without cause termination provisions. Further, CMS conceded that there is little risk of abuse for month-to-month holdovers that proceed on the same terms and conditions as the original lease or rental terms, so long as the holdover is for a limited duration. Therefore, under Phase II, holdovers that follow a lease agreement meeting all of the exception's requirements are permitted for up to six months.

Shifting from the Proposed Rule's interpretation of the exclusive use restrictions within the space rental exception as prohibiting subleases absent independent compliance with the exceptions' requirements, Phase II permits subleases as long as the lessor does not share, meaning use concurrently, or in lieu of, the rented equipment or space with the lessee. CMS made clear that concurrent shared use between the lessor and lessee is prohibited. For example, the Preamble explains that "exclusively" means that if a physician practice rents examination rooms to a DHS entity, the physician practice may not then use the rooms while the lessee or a sublessee is using them or renting them.

Reversing the Proposed Rule's interpretation that the space and equipment lease exceptions only apply to operating leases, the Preamble to the Phase II Final Rule establishes that the exceptions apply to any kind of bona fide lease arrangement, including capital leases.

Finally, Phase II clarifies that the requirement for the lease arrangement to be commercially reasonable in the absence of referrals contemplates the absence of Medicare DHS referrals to a DHS entity.

#### *2. Provisions Applicable Only to Equipment Leases*

Phase II adopts the Proposed Rule's interpretation that "per click" equipment rental payments qualify for the equipment rental exception, provided that the payments are fair market value and do not take into account the volume or value of the physician's referrals or other business generated by the referring physician. Alternatively, the Preamble indicates that under certain circumstances, equipment rental leases may fit within the new fair market value exception, as discussed at Section VI.B. However, this exception, which is limited to items and services provided by physicians, would not apply to space leases.

### **B. Physician Recruitment**

The Stark Law permits under certain conditions remuneration furnished to a physician by a hospital to induce the physician to relocate to the hospital's geographic area. The statute also authorizes CMS to impose additional conditions beyond those already delineated under the statute, authority that CMS utilized in Phase II. Phase II also creates a new regulatory exception for retention payments to physicians practicing in certain underserved areas, as described in Section XIII.I.

Under Phase II, FQHCs are permitted to make recruitment payments to physicians on the same basis as hospitals, provided that the arrangement does not violate the Anti-Kickback Statute or other federal or state laws or regulations governing billing or claims submission. CMS declined to extend the exception beyond FQHCs to other DHS entities because of its concern over what it believes are abusive recruitment arrangements, such as cross-town recruiting of an established physician practice by a competitor hospital.

Further, CMS explained the necessity, but need for refinement from the Proposed Rule, of the relocation requirement, instead of abandoning the requirement as some commenters had urged. Under the Phase II Final Rule, satisfying this requirement hinges on the location of the physician's practice, rather than the location of the physician's residence as suggested under the Proposed Rule.

Additionally, Phase II defines, for the first time, the hospital's "geographic area" in which the recruited physician must be placed. The exception requires the relocated physician to move his or her practice a specified distance (25 miles), or to have a specified percentage of patients (75% measured by revenue) be new to the practice. In meeting this latter test, CMS allows special rules for the start-up of a practice.

Phase II creates stand-alone exceptions for recruitment payments to hospital residents and indirect payments to existing group practices. In the Proposed Rule, CMS suggested that physician recruitment payments to hospital residents living in the area and indirect payments to a physician practice could fit, as an alternative, within the fair market value exception. In Phase II, CMS determined that recruitment payments cannot fit within the fair market value compensation exception because there is no exchange of service.

Recognizing the reality that newly recruited physicians prefer to join existing practices, Phase II extends the exception to cover recruiting payments to medical groups, provided certain stringent conditions are met. Most importantly, such arrangements need to be signed by the hospital or FQHC, the recruited physician, and the group. Where the group's overhead costs are charged or allocated to the new physician as part of an income guarantee, only the group's "actual additional incremental costs" that are attributable to the recruited physician are allowed. In addition, the group is prohibited from imposing additional conditions such as a non-compete, on the recruited physician, and the arrangement must comply with the Anti-Kickback Statute.

Phase II also clarifies and includes provisions in the Final Rule that establish that recruitment payments cannot be used to lock in physicians to the recruiting hospital, except when there is a separate employment agreement or contractual arrangement as permitted under the Bona Fide Employment exception. The Preamble indicates, however, that credentialing restrictions on physicians becoming competitors of a hospital would not violate this condition.

It should be noted, however, that documentation of community need is not a requirement of this exception although the IRS requires it for tax-exempt hospitals. It is also considered important for compliance with the Anti-Kickback Statute.

We note that although CMS has attempted in many ways to create a more flexible recruitment exception, certain requirements will likely require a significant

number of existing physician recruitment arrangements to be renegotiated.

### **C. Isolated Transactions**

The Phase II Final Rule significantly relaxes the restrictions in the Proposed Rule on the exception applicable to isolated transactions, such as the one-time sale of a property or medical practice.

CMS recognized the validity of commenters' suggestions that the six-month moratorium on additional transactions, coupled by the single payment requirement, is impractical because it precludes the opportunity to make necessary post-closing adjustments. Consequently, CMS expressly permits post-closing adjustments made within six months of the date of sale, so long as they are commercially reasonable even in the absence of other referrals or generated business. CMS clarified in the Preamble that the prohibition applies to all transactions because any type of financial relationship, not only those involving DHS, can create a financial relationship between a DHS entity and a referring physician that is prohibited unless it fits within a statutory or regulatory exception. CMS further declined to substitute a maximum number of allowable transactions for the existing prohibition on other unexcepted transactions within the six-month period following the sale.

The Final Rule now defines the term "transaction" to include persons or entities doing business, and as a result, entities are now able to participate in the exception. Moreover, the rule significantly expands the definition of an isolated sale to include installment payments, provided that the total aggregate payment amount is established before the first payment is made and does not take into account referrals or other business generated. CMS also imposes security requirements to assure payments.

### **D. Remuneration Unrelated to the Provision of Designated Health Services**

The Phase II Final Rule incorporates both technical changes and substantive interpretations that construe the exception for remuneration unrelated to the provision of DHS very narrowly. CMS rejected commenters' objections and adhered to the exceedingly narrow interpretation of the exception from the Proposed Rule that renders the exception available only for remuneration that is "wholly unrelated" to the provision of DHS.

Phase II establishes that remuneration is not "wholly unrelated" to the provision of DHS if it: (1) is any item, service or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles; (2) is given directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other physicians who are in a position to make or influence referrals; or (3) otherwise takes into account the volume or value of referrals or other business generated. CMS did reiterate its view that payments for the rental of residential property are the type of unrelated remuneration contemplated by the exception, and that payments for malpractice insurance and medical devices would be construed as related to the provision of DHS.

Viewing any item, service or cost that could be allocated to Medicare or Medicaid as related to DHS, CMS withdrew its proposed interpretation that administrative and utilization review services as not related to DHS. Further, the Preamble explains that even where

remuneration is not covered by cost reporting principles, the remuneration may relate to DHS by being given to medical staff who are in a position to make referrals.

Further, against objection, Phase II upholds the presumption that above fair market value payments for services unrelated to the provision of DHS are actually related to those services. Responding to the contention that CMS lacked the authority to impose an additional requirement that the payments be at fair market value, CMS stated in the Preamble that payments exceeding that threshold will be carefully scrutinized. CMS also rejected the suggestion that entities other than hospitals should be able to make unrelated DHS payments and qualify for the exception. Finally, despite recognizing that covenants not to compete are not necessarily equivalent to an obligation to make referrals, the Preamble clarified that these agreements clearly relate to DHS and consequently, need to fall within another exception to be acceptable.

#### **E. Certain Group Practice Arrangements with Hospitals**

Phase II adopts, with minimal modification, the Stark Law exception for group practice arrangements with hospitals in which the group furnishes DHS and the hospital bills for these services. Phase II adopts and codifies the Proposed Rule's suggestion that the "substantially all" test require that at least seventy-five percent (75%) of the DHS covered under the arrangement be services furnished to hospital patients by the group under the arrangement.

#### **F. Payments Made by a Physician for Items and Services**

This statutory exception protects payments by a physician either to a laboratory in exchange for the provision of laboratory services, or alternatively, to an entity as compensation for other items or services when these are furnished at a price consistent with fair market value. In Phase II, CMS interpreted the term "other items or services" to mean any kind of items or services that a physician might purchase. In addition, CMS did not adopt the Proposed Rule's suggested exception for discounts offered to physicians based on the volume of referrals when the discount is passed on in full to patients or their insurers and does not in any way benefit the physician. The Phase II Preamble explains that further consideration of this discount exception led CMS to conclude that legitimate discounts would fall within the range of values that is "fair market value."

### **XIII. COMMENTS AND CHANGES TO PHASE I COMPENSATION EXCEPTIONS, INCLUDING NEW PHASE II REGULATORY COMPENSATION EXCEPTIONS**

#### **A. Introduction**

In addition to the regulatory exceptions related to both ownership and compensation arrangements, Phase I also established six regulatory exceptions specific to compensation arrangements. Three of these, including the indirect compensation, fair market value, and risk-sharing exceptions, are discussed above in Sections V, VI.B, and VIII. The remaining three, including non-monetary compensation or gifts, compliance training, and medical staff incidental benefits were

modified to some degree in Phase II. These modifications, as well as six new compensation exceptions, are discussed below in the order they appear in the regulation.

#### **B. Charitable Donations By Physicians (Phase II)**

In the Phase II Preamble, CMS reassured commenters that a charitable contribution from a referring physician to a DHS entity will not violate the Stark Law. Although CMS could have simply excluded charitable contributions from the definition of remuneration, it has instead chosen to craft a regulatory exception, based on its reasoning that such a payment would constitute remuneration as defined in the statute. For a contribution to qualify for the exception, the recipient of the contribution must be a tax-exempt organization, and it must not solicit contributions specifically from physicians. For example, the exception permits contributions made to a broad-based fund-raising campaign that reaches physicians and non-physicians alike.

#### **C. Non-Monetary Compensation (Phase I)**

The only substantive revision to the Non-Monetary Compensation exception is that the \$300 limit on gifts to referring physicians will now adjust for inflation.

#### **D. Medical Staff Incidental Benefits (Phase I)**

Phase I created an exception for benefits incurred incidentally by the referring physician, such as free parking and the use of computer terminals while at the DHS entity. Phase I limited these benefits to those that occurred while the referring physician was at the DHS entity caring for patients. Commenters voiced concern that referring physicians are often involved in patient care while physically remote from the DHS entity, and urged CMS to modify the exception to include incidental benefits that facilitate these exchanges.

In response to these concerns, CMS modified the so-called "on campus rule" to accommodate the use of electronic or Internet services from a remote site. Accordingly, a DHS entity may provide a physician with a device such as a two-way pager or Internet connection to be used off-site, so long as the usage relates to services or activities that benefit the hospital or its patients (e.g., communication during urgent patient care situations). Phase II also expands the scope of the exception beyond hospitals to include any DHS entity that has a bona fide medical staff.

The exception does not apply if the physician would already employ the technology for his or her own practice, as when, for instance, the physician already had an Internet connection in his or her own office. The referring physician's use of a DHS entity's health information system is addressed in a separate exception discussed below.

Similar to the non-monetary compensation exception, Phase II revises the twenty-five dollar (\$25.00) per occurrence limit of the incidental benefits exception to adjust for inflation. Phase II also eliminates the requirement that incidental benefits be comparable to those offered at hospitals in the same region.

#### **E. Compliance Training (Phase I)**

Phase II retains the compliance training exception, but in three ways substantially expands its coverage to address commenters' concerns that the Phase I exception was too narrow to serve the OIG's broadly-stated goals for self-policing and voluntary compliance.

First, the exception now includes all DHS entities, rather than merely hospitals.

Second, Phase II includes training for a physician's office staff.

Finally, and perhaps most importantly, the exception now includes compliance training for any federal, state or local law, regulation, or rule that in any way governs the conduct of the party receiving training, rather than merely training as to government benefits programs. Training held outside the entity's service area does not come within the exception, ostensibly because travel to the site could confer an additional benefit upon the referring physician. As in Phase I, the exception also excludes continuing medical education ("CME"). CME, however, may be covered under the non-monetary compensation exception, depending on the program's content and the CME requirements of the state's licensing body.

#### **F. Referral Services (Phase II)**

Phase II carves out two new exceptions for conduct that complies with a safe harbor of the Anti-Kickback Statute. The first of these exceptions includes any arrangement that fits within the safe harbor for referral services. See Section XV below for a discussion of the interrelationship of the Anti-Kickback Statute and its safe harbors to the Stark Law.

#### **G. Obstetrical Malpractice Insurance Subsidies (Phase II)**

Similar to the physician referral service exception, Phase II now incorporates by reference the obstetrical malpractice insurance subsidies safe harbor.

#### **H. Professional Courtesy (Phase II)**

Phase II also exempts professional courtesies from the compensation prohibition. This common and longstanding practice, whereby the DHS entity furnishes medical services at no cost or at a reduced cost to referring physicians and their family and staff, is permitted where the courtesy is offered without regard to the volume or value of referrals generated, is a service routinely provided by the DHS entity, and other requirements are met.

#### **I. Retention Payments in Underserved Areas (Phase II)**

In response to commenters' concerns about physician turnover in underserved areas, Phase II provides a new exception for retention payments from a DHS entity hospital or FQHC to a referring physician, irrespective of the physician's specialty. To qualify for the exception, the physician must currently practice within a HPSA, or, as explained below, obtain an advisory opinion. The physician must also have a firm written recruitment offer, including salary, from another hospital or FQHC. Except as explained below, the offer must require the physician to relocate his or her practice outside of the current hospital's service area.

Further, CMS requires the usual prophylactic rules, for example that the arrangement must be set out in writing, cannot be conditioned on the physician's referral of patients to the hospital, must allow the physician to establish staff privileges at any other hospital except as restricted under an allowable separate employment or services contract, and must comply with the Anti-Kickback Statute.

CMS limits the amount of the retention payment to the lesser of: (1) the difference between the physician's

current income from physician and related services and the income proposed in the recruitment offer, calculated over no more than a twenty-four month period using the same methodology; or (2) the reasonable costs the hospital or FQHC must expend to recruit a new physician as a replacement. A hospital or FQHC may offer retention payments to a particular physician no more frequently than once every five years. Retention payments paid indirectly to the physician through a physician practice are not permissible.

Finally, the regulation gives CMS the authority to determine on a case-by-case basis, through advisory opinions, whether the physician is serving in areas with a demonstrated need that do not qualify as HPSAs. Additionally, the Secretary may waive, through an advisory opinion, the relocation requirement for a physician practicing in a HPSA or other underserved area.

Both of these advisory opinion processes are new in that this is the first time CMS is following the OIG process of case-by-case exceptions. Previously, CMS limited its advisory opinions to answering questions whether an arrangement was prohibited by the Stark Law. It will be very interesting to follow how many providers avail themselves of this process and how freely CMS creates exceptions. While CMS indicated in the Preamble that it will use this authority sparingly in granting health manpower need exceptions, it may well be faced with the reality that the hospital will lose the physician in question and then need to turn around and pay more money for a new recruit without needing to justify any demonstrated need to CMS.

#### **J. Community-Wide Health Information Systems (Phase II)**

In addition to the portable technology provision in the incidental benefits exception described above, Phase II also adds a separate exception for hardware and software that enable a referring physician to access the DHS entity's health information infrastructure. CMS does not consider this to be remuneration because it confers a benefit upon the DHS entity and facilitates patient care. A community-wide health information system meets this exception if it: (1) is available to all practitioners; (2) allows for sharing of electronic health care records; (3) does not replace hardware or software that the physician would purchase for his or her own practice; (4) does not take into account the volume or value of referrals; and (5) does not violate the Anti-Kickback Statute.

### **XIV. REPORTING REQUIREMENTS AND SANCTIONS (PHASE II)**

Inadvertently, CMS omitted provisions explaining the reporting requirements and sanctions from the Preamble to the Phase II Final Rule. CMS issued a technical correction on April 6, 2004 with these Preamble sections.

#### **A. Reporting Requirements**

Under the Stark Law, all entities that provide items or services payable under Medicare must comply with the reporting requirements. In the Proposed Rule, CMS made clear that it did not intend to require providers to submit reporting information until a final rule was published.

In responding to comments, CMS revised the reporting requirements in the following ways. First, it re-

tained the statutory requirements to allow CMS to collect information on: (1) UPIN numbers of the referring physician with a financial relationship; and (2) the covered items and services provided by the DHS entity.

Second, CMS retained the provision in the Proposed Rule waiving all reporting requirements for DHS entities providing twenty or fewer Part A or B services during a calendar year or DHS provided outside the United States. For physicians with a reportable financial relationship (see discussion below), CMS may collect information on the nature of the financial relationship as evidenced in records that the entity knows or should know about “in the course of prudently conducting business.” This information would include, but is not limited to, records that the entity is already required to retain to comply with IRS, Securities Exchange Commission, and Medicare and Medicaid program rules

A reportable financial relationship includes any ownership or investment interest or any compensation arrangement, except ownership arrangements meeting the exceptions for publicly traded entities and mutual funds. This means that DHS entities whose shares or debt instruments are so traded and meet these exceptions need not keep track of whether its referring physicians own an interest in the entity. The Preamble clarified that this exemption only applies to shareholder information and that DHS entities must report other financial relationships with referring physicians who are shareholders, such as personal service arrangements.

CMS appears to have backed off completely in requiring the regular submission of such information with updates as financial relationships change. This was the approach CMS first used in the 1995 Proposed Rule when it required entities furnishing clinical laboratory services to submit detailed financial information on prescribed forms. This approach was codified in the Stark I Final Rule in 1995. However, in the 1998 Proposed Rule, CMS indicated a softening of this position, suggesting for example only annual reporting.

Now in the Phase II Final Rule, CMS indicates that it does not even intend to issue any reporting forms at all. Although the regulation preserves CMS’s right to collect financial information, if it decided to create a form it would need to obtain Office of Management and Budget approval.

### **B. Sanctions**

As mentioned above, the Preamble to Phase II inadvertently omitted an explanation of the sanction provisions. The technical correction confirmed that Phase II makes no changes to the existing sanction provisions.

Violations of the prohibition on physician self-referrals may result in either Medicare’s nonpayment of claims for DHS provided as a result of a prohibited referral, an obligation to refund payment amounts, or for a knowing violation, CMP liability of up to \$15,000 per violation or \$100,000 per arrangement. The CMP authority is enforced by the OIG and is not the subject of this rulemaking.

Because each time an entity submits a claim for DHS resulting from a prohibited referral there is a violation, the \$15,000 per violation CMP coupled by the denial of payment sanction, can lead to substantial amounts even for limited infractions of the rules.

Significantly, in the Preamble of the Final Rule, CMS made clear that under the Stark Law physicians are not liable for payment recoupments for claims submitted in

violation of the law, but are liable only for CMPs and only where the government must prove the physicians acted with knowledge of the violation.

## **XV. DIFFERENCES BETWEEN THE STARK LAW AND THE FEDERAL ANTI-KICKBACK STATUTE**

The Stark Law differs from and is independent of the Anti-Kickback Statute in important ways. Whereas the Stark Law applies only to physician referrals, the Anti-Kickback Statute applies to all referral sources and prohibits other conduct, such as arranging for or recommending items, services or facilities. Unless knowledge is shown, there is no penalty for a referral made in violation of the Stark Law, only the denial or recoupment of payment for the item or service rendered.

By contrast, the Anti-Kickback Statute is a criminal statute, the violation of which is punishable by fines, imprisonment, or both. Accordingly, the Anti-Kickback Statute requires wrongful intent for a violation of its provisions, while the Stark Law does not.

The Anti-Kickback Statute also provides for regulatory safe harbors for certain business conduct the government determines is innocuous or beneficial even if there is a possible taint of money and referrals. If a provider meets all of the standards of a particular safe harbor, the conduct is immune from prosecution. Failure to comply fully with a safe harbor, however, has no legal effect; rather if the government objects to the arrangement it must still prove illegal intent to induce referrals. By implication, if an arrangement substantially – but not fully — complies with a safe harbor, there is no penalty; it merely means that the parties will not be protected by that safe harbor.

One of the confusions between the Stark Law and Anti-Kickback Statute is that many of the Stark Law exceptions were modeled after the Anti-Kickback Statute’s safe harbors. In both cases, the fundamental objective is the same: to create a set of prophylactic rules that dissipate any potential influence of money on referral decisions.

However, two important distinctions must be kept in mind. First, unlike the result of substantial compliance with an Anti-Kickback safe harbor (no penalty), failure to comply *fully and completely* with a Stark Law exception means that the entire financial arrangement is not in compliance with the statute. Second, CMS’s position is that full compliance with a Stark Law exception is irrelevant to compliance with the Anti-Kickback Statute.

CMS confuses the supposed distinction between the two statutes in two ways. First, there are certain exceptions, such as fair market value and indirect compensation arrangements, that are conditioned on compliance with the Anti-Kickback Statute or an applicable safe harbor. Second, in response to Phase I comments, CMS promulgated two exceptions in Phase II for arrangements that comply with the safe harbors for referral services and obstetrical malpractice insurance subsidies. Each of these exceptions is discussed in detail in Sections XIII.F and XIII.G above.

We find troubling CMS’s continued reliance on Anti-Kickback Statute compliance as a condition for qualifying under certain Stark Law exceptions. This approach introduces intent as an element of the Stark Law analysis, which is inconsistent with CMS’s goal of providing clear, bright-line rules.

We also were not satisfied with CMS’s explanation that this approach is required by the statute’s dictate

that any regulatory-created exceptions must pose “no risk of abuse.” OIG has had close to fifteen years of drafting safe harbors, and has sufficient experience in developing prophylactic rules that minimize abuse, without resorting to an analysis of whether there is unlawful intent to induce referrals as a condition of complying with the Stark Law.

On the other hand, we strongly agree with CMS’s decision to tie the Anti-Kickback Statute safe harbors to

the Stark Law exceptions. We suggest that the OIG should, in turn, adopt Stark Law exceptions as safe harbors.

Indeed, we believe that as long as an arrangement is covered by the Stark Law, there is no agreement or condition for referrals (both of these conditions being important), and the arrangement complies with a Stark Law exception, the Office of Inspector General should grant it safe harbor protection as well.

## EXHIBIT A

<b>TERMS OF EXCEPTION</b>	<b>Group Practice Physicians [1877(h)(4); 411.352]</b>	<b>Bona Fide Employment [1877(e)(2); 411.357(c)]</b>	<b>Personal Service Arrangements [1877(e)(3); 411.357(d)]</b>	<b>Fair Market Value [411.357(l)]</b>	<b>Academic Medical Centers [411.355(e)]</b>
<b>Must compensation be “fair market value”?</b>	No	yes - 1877(e)(2)(B)(i)	yes – 1877(e)(3)(A)(v)	yes – 411.357(l)(3)	yes - 411.355(e)(1)(ii)
<b>Must compensation be “set in advance”?</b>	no	no	yes – 1877(e)(3)(A)(v)	yes – 411.357(l)(3)	yes - 411.355(e)(1)(ii)
<b>Scope of “volume or value” restriction</b>	DHS referrals – 1877(h)(4)(A)(iv)	DHS referrals – 1877(e)(2)(B)(ii)	DHS referrals or other business – 1877(e)(3)(A)(v)	DHS referrals or other business – 411.357(l)(3)	DHS referrals or other business - 411.355(e)(1)(ii)
<b>Scope of productivity bonuses allowed</b>	personally performed services and “incident to”, plus indirect – 1877(h)(4)(B)(i)	personally performed services– 1877(e)(2)	personally performed services – 411.351 (“referral”) and 411.354(d)(3)	personally performed services – 411.351 (“referral”) and 411.354(d)(3)	personally performed services - 411.351 (“referral”) and 411.354(d)(3)
<b>Are overall profit shares allowed?</b>	yes – 1877(h)(4)(B)(i)	no	no	no	No
<b>Written agreement required?</b>	no	no	yes, minimum 1 year term	yes (except for employment), no minimum term	Yes, written agreement(s) or other document(s)
<b>Physician incentive plan (PIP) exception for services to plan enrollees?</b>	no, but risk-sharing arrangement exception at 411.357(n) may apply	no, but risk-sharing arrangement exception at 411.357(n) may apply	yes, and risk-sharing arrangement exception at 411.357 may also apply	no, but risk-sharing arrangement exception at 411.357(n) may apply	no, but risk sharing arrangement exception at 411.357(n) may apply

Source: CMS