



**CMS Stark II (Phase III) Final Rule**

**Prepared for:**

**Health Care Clients**

**October 4, 2007**

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## MEMORANDUM

TO: HEALTH CARE CLIENTS  
DATE: October 4, 2007  
RE: Stark II (Phase III) Final Rule

### I. INTRODUCTION & BACKGROUND

#### A. Issuance of Stark II (Phase III) Final Rule

On July 12, 2007, the Centers for Medicare & Medicaid Services (“CMS”) issued its 2008 Medicare Physician Fee Schedule proposed rule (“2008 MPFS Proposed Rule”), which included a number of significant, if not controversial, changes to the regulations that implement the federal prohibition on physician self-referral of Medicare patients, also known as the Stark Law.<sup>1</sup> In addition, more than three years after Phase II of the regulations were published, CMS published what it refers to as “Phase III” of the Stark regulations. Phase III, which was published in the Federal Register on September 5, 2007,<sup>2</sup> becomes effective on December 4, 2007.

Unlike the 2008 MPFS Proposed Rule, Phase III primarily provides clarification regarding interpretation of existing Stark regulations. Phase III does not establish any new exceptions or safe harbors to the Stark Law. It does, however, make a number of important changes to existing regulatory text including the addition of a new “stand in the shoes” provision for physicians that was referenced in the 2008 MPFS Proposed Rule, the elimination of the safe harbor for hourly compensation based on national survey data, and the expansion of the

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<sup>1</sup> Social Security Act § 1877; 42 U.S.C. § 1395nn. We addressed the proposed changes in a July 24, 2007, memorandum titled “Update on Important Stark Developments,” which is available on our internet site at [http://www.reedsmith.com/\\_db/\\_documents/hc0706.pdf](http://www.reedsmith.com/_db/_documents/hc0706.pdf).

<sup>2</sup> 72 Fed. Reg. 51012 (2007).

physician recruitment safe harbor.<sup>3</sup> This memorandum describes significant changes made to the regulatory text and highlights substantive discussions and clarifications CMS provided in response to public comments.

## **B. Abbreviated Statutory and Regulatory History**

Phase III continues the long and seemingly endless evolution of a Congressional initiative to address perceived abuses involving physician self-referral of patients that began 18 years ago. In brief, “Stark I,” named after its chief legislative sponsor, Representative Fortney “Pete” Stark (D-CA), was enacted as part of the Omnibus Budget Reconciliation Act of 1989. Stark I, which became effective January 1, 1992, generally prohibits physicians from referring Medicare patients to clinical laboratories with which those physicians or their immediate family members have certain financial relationships, with certain exceptions. Congress has amended Stark I on several occasions, most significantly in the Omnibus Budget Reconciliation Act of 1993 (“OBRA ‘93”).

The OBRA ‘93 physician self-referral limitations, which became known as “Stark II” or the “Stark Law,” expanded the self-referral limitations from clinical laboratory services to numerous other “designated health services” (“DHS”) and generally became effective January 1, 1995. Stark II also extended the physician self-referral restrictions to Medicaid programs, and it provided for additional statutory exceptions. Congress again amended the list of covered DHS in the “Social Security Act Amendments of 1994.”

On August 14, 1995, CMS (formerly referred to as the Health Care Financing Administration or “HCFA”) published final regulations to implement the Stark I restrictions. Although the Stark I regulations did not technically apply to the expanded Stark II framework, HCFA indicated that the Stark I interpretations likely would appear in the subsequent Stark II regulations and would, in the interim, direct the agency’s assessment of referral arrangements under Stark II.

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<sup>3</sup> CMS has posted a redline version of the Stark regulations that highlights all revisions to the regulatory text on its website at [http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/Unofficial\\_Redlined\\_411\\_350.pdf](http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/Unofficial_Redlined_411_350.pdf).

HCFA issued its Proposed Phase II Rule on January 9, 1998.<sup>4</sup> The Proposed Rule was criticized for being overly complex and for including interpretations of various aspects of the Stark Law that would have made its application very broad. HCFA attempted to address these criticisms when it published its first Stark II final rule on January 4, 2001.<sup>5</sup> This rule, dubbed “Stark II (Phase I)” implemented only three subsections of the Stark Law – the general prohibitions, the exceptions applicable to both ownership and compensation arrangements, and the related definitions as applied to the Medicare program. These provisions generally went into effect January 4, 2002, with certain exceptions.

On March 26, 2004, CMS issued an interim final rule referred to as “Stark II (Phase II)” which addressed most of the remaining issues not implemented in Phase I, including certain ownership and investment exceptions and compensation exceptions. It also created several new regulatory exceptions for “nonabusive” financial relationships and responded to public comments on the Phase I rule.<sup>6</sup>

This memorandum addresses Phase III of the rulemaking, which primarily focuses on clarifying the existing regulatory safe harbors developed during Phases I and II.

## **II. GENERAL PROHIBITIONS UNDER THE STARK LAW**

### **A. Scope of General Prohibition**

The Stark Law generally prohibits a physician from referring Medicare patients to receive certain designated health services, or DHS, from an entity with which the physician has a financial relationship. Specifically, the Stark Law states that:

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with

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<sup>4</sup> See 63 Fed. Reg. 1659 (1998).

<sup>5</sup> 66 Fed. Reg. 856 (2001). A February 28, 2001 Reed Smith client memo on the Phase I rule titled “HCFA’s Final Stark II Regulations With Comment Period (Phase I)” is available on our internet site at: [http://www.reedsmith.com/\\_db/\\_documents/hc0105.pdf](http://www.reedsmith.com/_db/_documents/hc0105.pdf).

<sup>6</sup> 69 Fed. Reg. 16054 (2004). An April 28, 2004 Reed Smith Client memo on the Phase II rule titled “CMS Stark II (Phase II) Final Rule” is available on our internet site at [http://www.reedsmith.com/\\_db/\\_documents/hc0408.pdf](http://www.reedsmith.com/_db/_documents/hc0408.pdf).

the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare.<sup>7</sup>

The term DHS includes: (i) clinical laboratory services; (ii) physical therapy, occupational therapy and speech language pathology services; (iii) radiology and certain other imaging services; (iv) radiation therapy services and supplies; (v) durable medical equipment and supplies; (vi) parenteral and enteral nutrients, equipment and supplies; (vii) prosthetics, orthotics, and prosthetic devices and supplies; (viii) home health services; (ix) outpatient prescription drugs; and (x) inpatient and outpatient hospital services. The definition of DHS has not been changed by Phase III.

## **B. Definition of “Entity”**

Currently, the term “entity” essentially refers to the provider that submits a claim to Medicare for the DHS ordered by a physician.<sup>8</sup> CMS indicates in Phase III that significant changes to the definition of “entity” may be forthcoming. In fact, in the 2008 MPFS Proposed Rule CMS proposed to expand the definition of an “entity” to include not only providers that submit claims and are paid by the Medicare, but also, for example, physician-owned entities that furnish items or services to the DHS entity submitting Medicare claims.

## **C. Broad Interpretation of “Financial Relationships”**

**1. *General Definition.*** Section 411.354 sets forth the criteria for determining whether there is a financial relationship between a physician and a DHS entity and, if so, how that relationship should be classified for purposes of determining which exception(s) may be used to protect the arrangement. A “financial relationship” can be any of the following: (a) a direct ownership or investment interest; (b) an indirect ownership or investment interest; (c) a direct compensation arrangement; or (d) an indirect compensation arrangement. CMS’s comments and regulatory changes focus primarily on revising the definition of “indirect compensation” in a manner designed to significantly limit the ability of physicians to rely on the

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<sup>7</sup> See 42 U.S.C. § 1395nn; 42 C.F.R. § 411.353. We note that, although the Omnibus Reconciliation Act of 1993 expanded the Stark Law to also apply to Medicaid programs, CMS has never taken the step to similarly expand the regulatory text to also cover physician self-referral of Medicaid patients, even though such an expansion was anticipated as part of the Phase III rulemaking.

<sup>8</sup> See 42 C.F.R. § 411.351 – *Entity*.

“indirect compensation” definition or exception by requiring physicians to now “stand in the shoes” of their group practices.

**2. *Narrowed Definition of Indirect Compensation Relationship.*** Under the regulations currently in effect, a physician has an indirect compensation relationship with a DHS entity if: (1) between the physician and the DHS entity there exists an unbroken chain of at least one other individual or entity that has a financial relationship with the DHS entity (e.g., the physician’s group practice); (2) the physician receives aggregate compensation from the interposing entity that varies with or takes into account the volume or value of referrals or other business the physician generates for the DHS entity; and (3) the DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with or takes into account the volume or value of referrals or other business the physician generates for the entity.

For example, a cardiology group has a contract with a hospital to perform professional interpretations of coronary CTA studies for which the group is paid a “per interpretation” fee. The cardiology group subsequently agrees to pay its cardiologists a fee for each interpretation the cardiologists read for their own patients who receive imaging services at the hospital. In this scenario the cardiologist would have an indirect compensation relationship with a DHS entity (i.e., the hospital) since there is one entity between the cardiologist and the hospital (i.e., the group practice) and the physician receives compensation from the group practice that takes into account the volume of referrals for DHS (i.e., imaging studies) the cardiologist generates for the hospital. Because the cardiologist in this example has only an indirect relationship with the hospital, the financial relationship between the hospital and the cardiology group need only comply with the requirements of the “indirect compensation exception” rather than the more onerous requirements of the “personal services exception.”

In Phase II, CMS solicited comments on whether physicians should be required to “stand in the shoes” of their group practices for purposes of determining whether they have a direct or indirect compensation arrangement with a DHS entity. In response to the comments and in an effort to “close an unintended loophole” in the current definition of “indirect compensation,” which permits many more arrangements to qualify as “indirect” than CMS anticipated (or simply fall outside of the Stark law altogether), CMS has added two new provisions that require physicians to “stand in the shoes” of their physician organizations.<sup>9</sup> CMS

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<sup>9</sup> 72 Fed. Reg. 51026.



anticipates that a significant number of compensation arrangements involving physician practices that previously were either: (1) determined not to create an indirect compensation relationship because the physician's compensation from the group practice was not tied to DHS referrals or did not meet the "knowledge" standard, or (2) qualified for protection under the "indirect compensation" exception will now be reclassified as direct compensation relationships. As a result, such arrangements will need to be reviewed and possibly restructured to meet the requirements of an applicable exception for direct compensation relationships (e.g., equipment rental, personal services).

a. *"Physician organization."* Perhaps the most significant definitional addition in Phase III is the introduction of the definition for "physician organization." In order to effectuate the "stand in the shoes" requirement, CMS created a new definition to describe the types of entities that will be subject to collapse of physician ownership for purposes of establishing a direct compensation relationship. The types of entities that will be subject to the new provision are "physician organizations," which are defined as follows:

Physician organization means a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352.

The introduction of this expansive definition of the physician practice vehicles used by physicians who refer to DHS entities is a cornerstone of CMS's stated intent to "close a loophole" it believes was inadvertently created by broad use of the "indirect compensation arrangement" analysis. CMS's objective here is clear: when a referring physician practices medicine in any type of physician organization, broadly defined, one must determine whether that relationship between the physician organization (as a proxy for the individual physician) and the DHS entity receiving the referrals from the organization's physicians meets one of the exceptions for direct compensation arrangements (e.g., for equipment or space leases, or for personal services arrangements). In other words, physicians will now be deemed to be "standing in the shoes" of the physician practice organization that contracts with the DHS entity. The fair market value ("FMV") requirement and other standards of the direct compensation arrangement exceptions will apply, rather than the "indirect compensation arrangement" definition or exception.

b. *Reed Smith Comments.* CMS's change here – to broaden the types of physician practice organizations that will be deemed to be the “alter egos” of individual referring physicians for Stark law purposes - is an efficient way to achieve its policy objective of shifting the analysis of these arrangements from “indirect” to “direct” financial relationships. We question, however, whether CMS's policy change was necessary because the indirect compensation analysis was appropriate for many arrangements where entities were interposed between the referring physician and the DHS entities, and adequate safeguards were already in place.

We note that the term “physician practice,” included as a type of “physician organization,” is not itself defined and likely will be construed as a “catch-all” for any type of coordinated physician clinical enterprise for purposes of applying the “standing in the shoes” analytical approach. We also note that the term “physician organization” does not include a limited liability company (“LLC”), limited partnership, corporation, or other entity that may be wholly-owned by physicians but which does not function as a physician practice, such as an LLC used by a group of physicians to invest in a medical office building, diagnostic testing center, clinical laboratory, leasing company, or management company. The failure to include such physician-owned entities in the definition of a “physician organization” is curious given the amount of time and attention CMS devoted in the 2008 MPFS Proposed Rule to expressing its discomfort with and intent to significantly curb the use of certain “under arrangement” relationships and joint ventures involving physicians, since these arrangements typically involve physician-owned investment entities rather than physician practices. As a result, many of the arrangements CMS questioned in the 2008 MPFS Proposed Rule and presumably desired to target with the implementation of the “stand in the shoes” provision can continue to be protected under the indirect compensation exception. It is possible that CMS could address this issue in future rulemaking.

c. *“Stand in the Shoes”.* Under the new “stand in the shoes” provision set forth at 411.354(c)(1)(i), a physician is deemed to have a direct compensation relationship with a DHS entity if the only intervening entity between the physician and the DHS entity is his or her physician organization (as defined above). In addition, a physician is deemed to “stand in the shoes” of the physician organization with which the physician has a direct financial relationship. As a result, the physician is deemed to have the same compensation arrangements with the same parties and on the same terms as the physician organization has with the DHS entity. By standing in the shoes of the

physician organization, the physician will then have a direct compensation relationship which then must comply with an applicable exception (other than the indirect compensation exception).

**3. *Grandfather Clause for Former Indirect Relationships.*** CMS recognizes that, if the “stand in the shoes” provision was fully implemented and applicable to all arrangements as of December 4, 2007, many existing arrangements that were properly structured to qualify for protection under the indirect compensation exception prior to this new provision may no longer qualify under an exception. In an effort to soften the potential impact of the new provision, CMS has developed a phase-in period for compliance. Any arrangements that were entered into prior to September 5, 2007 and as of that date satisfied the requirements of the indirect compensation arrangements exception can continue without amendment during the original term of the agreement or, if the agreement is in a renewal period, the current renewal term. However, once the original term or the current renewal term expires, the “grandfathered” arrangements will become subject to the “stand in the shoes” provision and will, at that time, need to be structured to comply with an appropriate “direct compensation” exception (e.g., space rental, personal services).

It is important to note that the “grandfather” clause cannot be used to protect any arrangements which, prior to Phase III, were determined not to create either a direct or indirect compensation relationship and, thus, were not structured to meet the indirect compensation exception but now as a result to the “stand in the shoes” provision will create a direct relationship for a physician. For example, a hospital enters into a medical director agreement with an orthopedic group practice that regularly refers patients to the hospital for outpatient hospital services. The orthopedic group is paid a fixed monthly amount for its services. The orthopedic practice compensates its physicians by equally sharing the practice’s profits. Thus, none of its physicians receives compensation that is directly based on the volume or value of DHS referrals they make to the hospital. As a result, the medical director agreement between the hospital and the orthopedic group was, prior to Phase III, determined not to create any type of direct or indirect compensation arrangement between the physicians and the hospital. However, as of December 4, 2007, the medical director agreement will create a direct compensation arrangement between the hospital and each of the orthopedic group physicians since those physicians will “stand in the shoes” of their group. As a result, the medical director agreement will, as of December 4<sup>th</sup>, need to comply with the requirements of the personal services exception because the arrangement did not qualify for the indirect compensation exception prior to September 5, 2007.

**4. *Exception for Security Interest in Equipment.*** In addition to revising the definition for “indirect compensation,” CMS also revised the definition of an “ownership interest” by expanding the types of relationships that will not be considered investment or ownership interests. It is not uncommon in a sale of equipment that involves installment payments for the agreement to specify that the seller retains a security interest in the equipment in the case of nonpayment. In Phase II, CMS stated that a loan to a hospital that is secured by a particular piece of equipment would be considered an ownership interest in part of a hospital, but such a one-time sale of property using installment payments could possibly qualify for protection under the “isolated transactions” exception set forth at 411.357(f).<sup>10</sup> CMS reconsidered the issue and decided that a security interest in equipment sold by a physician to a hospital under an installment loan does not, in fact, create an ownership or investment interest in the hospital. Instead, such a transaction merely creates a compensation arrangement between the parties which must qualify under an applicable compensation exception if the physician makes DHS referrals to the hospital. In order to eliminate any future uncertainty regarding this issue, CMS revised the definition of “ownership or investment interest” to clearly state that the definition does not include a security interest held by a physician in equipment sold to a hospital by the physician and financed through a loan from the physician to a hospital.

**5. *Clarification Regarding Compensation Conditioned on Referrals.***

Although many of the Stark exceptions require that compensation not be based on volume or value of referrals, Phase I established at § 411.354(d)(4) a special exception that, under certain circumstances, permits DHS entities to condition a physician’s compensation on compliance with certain referral requirements. Phase II attempted to further refine this exception to provide that it only applies to employment, managed care, or personal service agreements with physicians. However, the regulatory text was not as clear as it could be since it simply stated that a physician’s compensation from “an employer or under a managed care or other contract may be conditioned on...” As a result, the exception was interpreted by some as applying to any type of compensation contract with a physician rather than solely contracts for personal services. CMS corrected this provision to clearly indicate that the exception permitting a physician’s compensation to be conditioned on certain referral requirements applies only to contracts for the physician’s personal services.

CMS received numerous requests to entirely delete § 411.354(d)(4) on the basis that the exception conflicts with a provision in the Balanced Budget Act of 1997, which requires

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<sup>10</sup> 69 Fed. Reg. 16063, 16098 (2004).

that a hospital's patient discharge plan advise the patient of home health agencies that serve the area in which the patient resides and that the hospital identify any home agency to which the patient is referred and in which the hospital has a financial interest. The commenters assert that by requiring employed or contracted physicians to refer to the hospital's own home health agency as a condition of compensation, the hospital is thwarting its obligation to provide the patient with an informed choice. CMS declined to eliminate the exception and countered by stating that the hospital does not necessarily violate its obligations as long as the patient is provided with the required list and, after the patient expresses a choice, the hospital and the physician honor that choice.

#### **D. Sanction for Stark Violations**

To date, enforcement activities involving the Stark Law have been limited. Nevertheless, persons and entities subject to the Stark Law should understand potential liability exposure that can be created by non-compliance with this statute and its implementing regulations. The basic sanction under the Stark Law is nonpayment for DHS referred by a physician with an improper financial relationship with the DHS entity. In addition, an entity that collects payment based on a prohibited DHS referral must refund all collected amounts "on a timely basis."

The Stark Law is a "strict liability" statute because it does not require proof of intent to violate the law in order for the government to impose sanctions. Section 411.353 describes the basic prohibition on physician self-referral including a few limited circumstances in which sanctions will not be imposed for inadvertent, temporary noncompliance. In Phase I, CMS added a "safe harbor" at § 411.353(e) for Medicare payments made to a DHS entity if the entity did not have actual knowledge of, and did not act in reckless disregard of, the identity of the physician who made the DHS referral to the entity. In Phase II, CMS added an additional safe harbor at § 411.353(f) to permit a DHS entity to receive payment for DHS furnished during no more than a 90 day period of noncompliance if: (1) the financial relationship in question had been in full compliance with an exception for at least 180 consecutive days immediately preceding the date on which the relationship became noncompliant; (2) the financial relationship fell out of compliance for reasons beyond the entity's control but the entity promptly moved to address the noncompliance; and (3) the financial relationship does not violate the federal anti-kickback statute and complies with all other applicable federal and state laws.

CMS received a number of comments requesting that it broaden various aspects of the "noncompliance" safe harbors including extending the protection to the referring physicians,

expanding the 90-day claim submission period, shortening the 180-day compliance window and basing the 90-day time frame on the date the noncompliance was discovered rather than the date the noncompliance actually began. CMS declined to modify the existing non-compliance safe harbors. We note, however, that as discussed in our July 24<sup>th</sup> Memo, CMS solicited comments from the public regarding whether it should amend certain Stark exceptions to provide for an alternative method for satisfying the exception in instances where there has been an unintentional violation of a procedural or “form requirement” of the exception. Thus, although CMS is unwilling to modify the existing safe harbors, it is considering developing new, exception-specific safe harbors for certain types of noncompliance.

### **III. GROUP PRACTICE REQUIREMENTS**

A number of the exceptions discussed in the memorandum, including the in-office ancillary services exception, protect certain ownership or compensation arrangements involving a “group practice.” In order for an organization to qualify as a “group practice,” it must satisfy the criteria set forth in § 411.352 including a special rule on paying productivity bonuses and profit shares to physicians in the group practice.

#### **A. Profit Shares and Productivity Bonus**

1. *Clarifications to Existing Regulations.* Under existing regulations, a group practice may pay a “physician in the group practice” either a share of overall profits of the group or a productivity bonus based on services the physician personally performs (including services provided “incident to” the personally performed services) as long as the profit sharing or bonus is not determined in a manner that is “directly” related to that physician’s volume or value of DHS referrals. The rule has been interpreted as permitting a group to pay a physician a portion of the group’s overall profits that is based on volume or value of a physician’s “incident to” services.

In an effort to align the requirements of this regulation more closely with the statutory language, CMS is revising the rule to clarify that a productivity bonus can be based directly on services provided “incident to” a physician’s personally performed services but cannot be based on any other DHS referrals (e.g., diagnostic tests or hospital admissions). In addition, CMS revised §411.352(i) to specify that a physician may not be paid a share of overall profits if the payment is *directly* related to the volume or value of that physician’s DHS referrals, including referrals for “incident to” services. CMS recognizes that the term “overall profits” by

definition includes profits from “incident to” services but notes that such payment would be permissible since it is *indirectly* based on the value of “incident to” services.

**2. *Reed Smith Comments.*** CMS’s review of prior years’ changes reiterates just how narrow the scope of services has become that group practices can consider in calculating a physician’s productivity bonuses based on his or her “incident to” services. Following prior changes to Medicare reimbursement and coverage rules, a physician’s ordering, for example, of diagnostic x-rays, diagnostic laboratory tests, and other diagnostic tests (which are separately covered under section 1861(s)(3) of the Act) must be excluded from an “incident to” productivity bonuses calculation. This change from 2002-2003 severely restricts the scope of services (and usefulness) of the productivity bonus provisions for group practices.

**B. Definition of “Incident to”**

**1. *Inclusion of “Supplies” and Confirmation of Scope.*** As discussed above, CMS permits a group practice to pay profit shares and productivity bonuses to its physicians based on services personally performed or services “incident to” such personally performed services. Phase III simply clarifies that the term “incident to” includes both services and supplies (such as drugs) that are covered under the section 1861(s)(2)(A) of the Act.

**2. *Reed Smith Comments.*** The Phase III clarification that extends “incident to” coverage to supplies is a minor, yet helpful, confirmation that supplies properly fall within that term.

**C. Medical Foundation, Non-Profit, and Hospital-Owned Entities**

In addition to the above revision to the regulatory text, CMS responded to an assortment of questions from the public regarding the ability of certain organizations to qualify as a “group practice.”

**1. *Hospital-Owned Entity.*** CMS confirmed that a hospital could form a separate legal entity that was internally separated into divisions based on specialty for the purpose of employing physicians and, as long as the divisions were not themselves legal entities, the legal entity could potentially qualify as a “group practice” assuming it met all other requirements of § 411.352.

**2. Medical Foundation.** A commenter requested that CMS clarify that medical foundations qualify as “group practices.” CMS declined to make a blanket statement that all medical foundations are group practices, in part because it is aware of foundation models in which the foundation is not legally organized by two or more physicians as specified in Section 1877(h)(4)(A) of the Social Security Act (the “Act”). CMS advised that in order to qualify as a group practice a foundation must satisfy the “group practice” requirements just the same as any other legal entity.

As far as medical groups that contract with foundations to perform medical services, CMS commented that even though the medical services performed by the physicians of a medical group may be billed by a foundation pursuant to a contractual relationship it may, nevertheless, be possible for that medical group to qualify as a “group practice.” Although the medical group would not be directly billing Medicare or other third-party payors for its physicians’ services, CMS noted that “a group practice may count such services as services the physician provides through the group” for purposes of satisfying the requirement that “substantially all” of the patient care services provided by physician members of the group be billed under a billing number assigned to the group.<sup>11</sup>

**3. Nonprofit Group Practice.** Section 411.352(f)(1)(i) requires that a group practice have a centralized decision-making body that is representative of the group practice and that this body maintain effective control over the group’s assets and liabilities. One commenter requested clarification that, in the case of a tax-exempt, nonprofit group practice, the majority of the decision-making body can be composed of disinterested representatives of the community as is required by the IRS rules for a Section 501(c)(3) organization. CMS declined to revise the regulatory text and, instead, confirmed that nothing in the regulatory text requires that the decision-making body be a majority of physicians. The body must merely be “representative” of the group practice – which would include its physicians.

#### **IV. EXCEPTIONS RELATED TO BOTH OWNERSHIP & COMPENSATION**

##### **A. Physician Services**

**1. Deletes Errant Reference to Diagnostic Tests.** The “physician services” exception protects any referrals a physician makes for physician services that are DHS if those

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<sup>11</sup> 72 Fed. Reg. 50122.



services are furnished: (1) personally by another physician in the same group practice as the referring physician, or (2) under the supervision of another physician in the same group practice.<sup>12</sup> Subsection (3) of the exception has long stated that “incident to” services which are not physician services (e.g., diagnostic tests, physical therapy) cannot be protected under the “physician services” exception. As diagnostic tests can never be billed as “incident to” services, this reference in the regulatory text was incorrect. Thus, CMS deleted § 411.355(a)(3) since the section was incorrect and did not substantively add to the understanding or application of the exception.

**2. *Direct Contract and On-Site Requirement for Independent Contractors.***

In response to comments regarding the use of independent contractor pathologists who perform professional services off-site in “condo” labs, CMS reiterated that a “physician in the group practice” does, in fact, include independent contractor physicians. However, CMS modified the definition of “physician in the group practice” to specifically require that any independent contractor physician furnishing patient care services for the group must do so pursuant to a contractual arrangement directly with the group practice. In addition, CMS reiterated that the independent contractor must perform the patient care services “in the group practice’s facilities.” As a result, the physician service exception is not available to protect physician services performed in an off-site location by an independent contractor if that location is not part of the group’s facilities.

**B. In-Office Ancillary Services**

Despite repeatedly expressing concern in the 2007 MPFS Proposed Rule and the 2008 MPFS Proposed Rule regarding the growth of “pod” labs and other arrangements for ancillary services that are not closely connected to the operations of the physician practice billing for the services, CMS declined to make any substantive changes to the “in office ancillary services” exception. Instead, CMS merely addressed certain issues of concern expressed in the comments and is soliciting comments through the 2008 MPFS Proposed Rule as to whether the exception should be changed to curtail program or patient abuse.

**1. *“Some” Physician Services.*** Several commenters requested additional clarification regarding the part-time office requirement that “some” of the physician services furnished in the office be unrelated to the furnishing of DHS. CMS declined to revise the

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<sup>12</sup> § 411.355(a).

regulatory text, but stated that that when evaluating whether “some” physician services unrelated to DHS are performed in the office, CMS takes into account: (a) the nature of the group’s overall practice (for example, the specialties of the group’s physicians); (b) the full range of the referring physician’s practice; and (c) the actual operation of the office rather than its form on paper.<sup>13</sup> CMS warned that creating a satellite office that appears to satisfy the “same building” requirements but is, in fact, a sham because few, if any, physician services unrelated to DHS are performed in the office will result in claims denial.

**2. “Exclusive Use” of a Shared Facility.** One model used by physicians to provide DHS to their patients in a shared facility (*i.e.*, an imaging suite, clinical laboratory, physical therapy office) is a “shared expense” model under which the physicians may use the facility on an “as needed” basis and simply share the costs and administration of the DHS facility rather than entering into separate leases with the facility for specific blocks of time determined in advance. A commenter questioned whether such a “shared expense” model which permits simultaneous use of the DHS facility complies with the “same building” requirements of the in-office ancillary services exception. CMS responded that a physician utilizing a shared facility in the same building must control the facility and the staffing at the time the DHS is furnished to that physician’s patient and noted that, as a practical matter, “this likely necessitates a block lease arrangement.”<sup>14</sup> CMS further commented that “per use” fee arrangements are unlikely to satisfy the supervision requirement of the in-office ancillary services exception and may also implicate the federal anti-kickback statute.

These statements regarding the suspected inability of a “per use” lease arrangement to satisfy the “same building” requirements and the need for the parties to utilize a block lease arrangement are particularly important in that they directly address a source of continuing debate among health care counsel as to whether “per use,” “shared expense,” or similar business models that enable a physician to utilize a shared facility on an “as needed” basis are permissible. For the first time, CMS is voicing a relatively firm position that in order for a shared facility to satisfy the same building requirements the referring physician must lease the facility on a block-time basis - which is what would also be required of the parties if they desired to structure the lease to comply with the requirements of the equipment and space rental safe harbors to the federal anti-kickback statute. Thus, without any revisions to the actual

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<sup>13</sup> 72 Fed. Reg. 51033.

<sup>14</sup> *Id.*

regulatory text, it is possible that CMS may have now put a damper on “per use” lease arrangements for DHS facilities.

**3. *Entity with Identical Ownership Not “Wholly-Owned”.*** The billing requirements of the in-office ancillary services exception permit an entity that is wholly-owned by a group practice to bill for DHS under either the entity’s own billing number or a billing number assigned to the group practice. Commenters requested guidance as to whether an entity that is wholly-owned by the group practice members individually (as opposed to being wholly-owned by the group practice itself) under a structure identical to the ownership of the group practice could satisfy the billing requirements. CMS responded that the literal interpretation of the regulation requires that the entity be “wholly owned” by the group practice – not its individual members – and, thus, the entity would not qualify under the billing requirements.

### **C. Academic Medical Centers**

CMS made a number of changes to the exception for payments to faculty of academic medical centers (“AMCs”)<sup>15</sup> intended to clarify rather than substantively change the exception. First, CMS revised the regulatory text to clarify that compensation paid to a referring physician must meet all of the following conditions: (1) total compensation paid by each AMC component must be “set in advance;” (2) the compensation paid by all of the AMC components cannot, in the aggregate, exceed fair market value for the services provided; and (3) total compensation paid by each AMC component cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician for any component of the AMC.

In addition, CMS clarified in the preamble discussion that the governing body of each AMC component may approve or adopt its own agreement or other written documentation memorializing the relationships with other components rather than being required to use a single, master affiliation agreement adopted by all AMC components.

Finally, CMS made one substantive change to the exception which limits an AMC’s ability to count volunteer and courtesy faculty in determining whether the majority of medical staff physicians are faculty members. Under the revised formula, an AMC may count volunteer and courtesy faculty as faculty members. However, the AMC must then also count all

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<sup>15</sup> § 411.355(e).

physicians who are not faculty members that hold the same class of staff privileges as the volunteer and courtesy faculty in calculating the size of the total medical staff. Thus, if courtesy faculty hold limited courtesy privileges as the AMC, the AMC must count all other physicians who also hold courtesy privileges but who are not faculty members in determining the total size of the medical staff.

**D. Implants Furnished by an ASC**

No further changes were made to the exception that permits a physician-owner of an ASC to order an implant supplied during a surgery but not reimbursed as part of the composite ASC payment rate.<sup>16</sup> In the preamble to Phase III, CMS notes that this exception does not extend to DHS furnished and billed by the physician (rather than the ASC).

**E. Intra-Family Rural Referrals**

**1. *Definition of “Rural Area.”*** Currently, the “intra-family rural referrals” exception permits a physician to make referrals to a DHS entity with which the physician has a financial relationship if, among other requirements, the patient who is referred resides in a “rural area.”<sup>17</sup> CMS has relocated the definition of a “rural area” to § 411.351-Definitions and is revising the definition to make it consistent with the statutory exception for rural providers. The term “rural area” means an area that is not an “urban area” as defined in Medicare’s inpatient hospital services prospective payment system regulations. “Urban area” is defined in those regulations as follows:

(A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

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<sup>16</sup> § 411.355(f).

<sup>17</sup> § 411.355(j).

42 C.F.R. § 412.62(f)(ii).

The term “rural area” appears now to be defined rather broadly. The phrase “rural area” is used not only in the exception for “intra-family rural referrals” but also in the ownership exception for “rural providers” that furnish DHS and the physician recruitment exception. In all cases, other qualifying criteria must still be satisfied for protection under the applicable Stark exception.

**2. *Alternative Distance Test.*** In addition to clarifying the definition of a “rural area,” Phase III creates an alternative test for determining whether a physician may refer his or her immediate family member to a DHS entity with which the physician or family member has a financial relationship. Currently, such a referral is permitted only if no other provider is available to furnish the service in a timely manner either: (1) in the patient’s home, if required to be furnished in the home, or (2) within 25 miles of the patient’s home.

Phase III offers an alternative to the 25 mile test. Under the new test, a family member may be referred to a DHS entity if the DHS can not be provided within 45 minutes transportation time. The new test is intended to offer additional flexibility to the exception by considering terrain, weather conditions, speed limits, as well as distance. Physicians living in rural areas may be disappointed to learn, however, that if a physician relies on this alternative test, CMS suggests the physician retain a significant amount of documentation about the information used to determine the transportation time, including copies of web pages that provide mileage, drive time, and even weather reports.

## **V. EXCEPTIONS RELATED SOLELY TO OWNERSHIP INTERESTS**

### **A. Publicly-Traded Securities & Mutual Funds**

CMS received only one comment regarding the ownership exceptions for publicly traded securities<sup>18</sup> and mutual funds<sup>19</sup> and made no changes to these exceptions in Phase III. The sole commenter supported CMS’s clarification of the publicly traded securities exception, namely, that an investment interest (in securities) must be available to the public at the time the referral is made and not at the time the interest is acquired. CMS explained that compliance with this

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<sup>18</sup> § 411.356(a).

<sup>19</sup> § 411.356(b).

requirement should not be difficult as the relevant inquiry (i.e., whether the investment is available to the public when the referral is made) “turns on objective facts that are readily ascertainable to the physician or the entity furnishing DHS.”

## **B. Rural Providers**

CMS received comments on three issues related to the exception for an ownership or investment interest in entities that furnish DHS in a rural area.<sup>20</sup> In responding to such comments, CMS explained several points (as outlined below); it did not, however, make any substantive changes to this exception.

First, in response to a comment, CMS confirmed that, with respect to a physician’s ownership or investment interest in an entity that meets the rural provider exception, the arrangement need not also satisfy the in-office ancillary services exception. However, to the extent a physician also has a compensation arrangement with the DHS entity/rural provider, this separate/additional financial relationship would need to satisfy one of the exceptions for compensation arrangements (e.g., the in-office ancillary services exception).

Second, CMS commented on various aspects of the definition of “rural area.” (See Section IV.E. above). To begin, CMS declined to create a list of all zip codes that would be considered “rural” for purposes of this exception, as such an undertaking would require too many resources. Instead, CMS explained that, for purposes of Stark, a particular location is considered a rural area if it is not located in a metropolitan statistical area (“MSA”). To determine whether an entity is furnishing DHS in an MSA, CMS noted that the Office of Management and Budget’s web site provides a list of MSAs. CMS further noted that “Micropolitan Statistical Areas” are not within MSAs. As such, for Stark purposes, Micropolitan Statistical Areas are rural areas.

Finally, CMS explained that any physician who invests in an entity furnishing DHS in a rural area “takes a risk that the area will subsequently be classified as an urban area,” and, therefore, fall out of compliance with the rural provider exception. Accordingly, CMS declined to provide any protection to a physician’s ownership interest in a DHS entity that was furnishing DHS in a rural area at the time of the investment but has since been reclassified as urban. Further, CMS declined to provide alternative criteria for satisfying the rural provider exception under these circumstances (e.g., it refused to create an across-the-board exception for medically

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<sup>20</sup> § 411.356(c)(1).

underserved areas in which the nearest DHS entity was at least 30 miles away, as proposed by a commenter). According to CMS, Congress intended the rural provider exception to be very specific and narrowly defined.

### **C. Ownership Interest in a Whole Hospital**

CMS made no changes to the exception for an ownership or investment interest in a whole hospital,<sup>21</sup> but responded to several comments.

First, CMS reiterated its position that the exception was limited to referrals to a hospital for DHS provided by the hospital — protection is not extended to hospital-owned, separately-licensed subsidiary providers or suppliers (such as a home health agency, skilled nursing facility, or DMEPOS supplier).

Second, CMS explained again (as discussed above in Section II.C.4.) that a security interest in equipment sold to a hospital by a physician (and financed through a loan to the hospital) would not be viewed as an ownership interest in the hospital — it would be considered compensation arrangement instead. However, a security interest in the hospital itself would be considered an ownership interest in the hospital (and an indirect ownership interest in the hospital's subsidiaries).

Finally, CMS responded to a comment that it should more clearly define how it determines when a hospital is considered to be a “specialty hospital” that is “primarily engaged in” care and treatment of certain patients. CMS responded that, for purposes of implementing the (now-expired) 18-month moratorium on physician-ownership in “specialty hospitals” under the whole hospital exception, CMS considered a hospital to be “primarily engaged” in the care of cardiac, orthopedic or surgical patients if 45 percent of the hospital's Medicare cases were (or were projected to be) in Major Diagnostic Category (MDC) 5, Diseases and Disorders of the Circulatory System (cardiac), MDC 8, Diseases and Disorders of the Musculoskeletal System and Connective Tissue (orthopedic) or were surgical in nature. CMS noted that, in addition, it is considering whether to revise the CMS 885-A enrollment form to gather information necessary to determining whether a hospital is a “specialty hospital.”

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<sup>21</sup> § 411.356(c)(3).

## **VI. EXCEPTIONS RELATED SOLELY TO COMPENSATION ARRANGEMENTS**

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

1. *Overview of CMS's Comments/Changes.* CMS did not make any substantive changes to the exceptions for rental of office space<sup>22</sup> or equipment.<sup>23</sup> However, as discussed below, other Phase III changes impact the application of these exceptions. In addition, in the preamble to Phase III, CMS clarified several points related to these exceptions.

The first issue addressed by CMS was whether a lease could be amended prior to the termination of the agreement. CMS explained that changes to the rental charges (including changes to the methodology for calculating the rental charges) and changes to other terms that are materials to the rental charges (e.g., a change to the amount of space rented) “may jeopardize compliance” with the exception. More specifically, since rental charges (and the methodology to calculate such charges) must be set in advance, CMS reiterated that “the parties may not change the rental charges at any time during the term of the agreement.” Instead, the parties must terminate the agreement and enter into a new one (which may have different rental charges). However, CMS cautioned, this can only be undertaken after the first year of the original lease term has passed, and the new lease must be for a term of at least one year.

In contrast, amendments that do not relate to rental charges may be undertaken by the parties multiple times during or after the first year of the term of the lease (provided all aspects of the exception are satisfied). Moreover, amended agreements need not continue for an additional one year following the amendment if the original termination date is sooner. CMS explained that the lease exception requires a one-year term from the inception of the lease agreement, and, as such, the amended agreement may terminate on the original expiration date.

Second, CMS confirmed that the component of the lease exception that prevents the parties to a terminated lease from entering into another agreement is limited to prohibiting the same parties from entering into a new lease for all or part of the same space. Therefore, the parties are not prohibited from entering into a personal services agreement or a lease for different space — even if they terminate a lease within the first year of the term.

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22 § 411.357(a)

23 § 411.357(b).



Third, CMS declined to accept the argument of a commenter that turn-key “time share” leasing arrangements (where space, personnel, equipment, furniture, et cetera, is leased at certain intervals) should be protected under the exceptions for fair market value (“FMV”)<sup>24</sup> or payments by a physician.<sup>25</sup> CMS reiterated its position that space leases are not eligible for the FMV exception and did not believe the exception for payments by a physician should protect space leases either.

Fourth, in response to a comment regarding arrangements where physicians share certain equipment (without exclusivity), CMS noted that, irrespective of whether such arrangements were common in the industry, in order to meet the exception, a lessee must have exclusive use of space or equipment when the lessee uses the space or equipment. As a practical matter, CMS explained, this means that a lessee must lease space and equipment for established blocks of time.

Fifth, in response to questions regarding common areas, CMS defined “common areas” as “foyers, central waiting rooms, break rooms, vending areas, etc., to the extent that the areas are, in fact, used by the sublessee.” Further, CMS explained that common areas that contain “certain limited equipment may be shared, such as hallways used by non-physician staff to weigh patients or draw fluid samples.” However, the types of equipment that may be shared in common areas are limited to the types that are not usually separately leased. CMS provided only one example, however: scales. According to CMS, common areas do not include exam rooms.

Sixth, in response a question regarding tenant improvement allowances, CMS explained that, for accounting purposes, such allowances “should be accounted for in accordance with generally accepted accounting practices.” On the other hand, for purposes of determining FMV under the Stark exception for leases, the proper treatment of tenant improvement allowances will vary based on the facts and circumstances of each case. CMS posited, however, “that if a lessor provides improvements for the benefit of a physician lessee that are unlikely to be chargeable to a subsequent tenant, the lessor should allocate the entire cost of the improvements to the lessee.” In contrast, improvements that the lessor reasonably expects to charge to subsequent lessees may be “allocated over their expected useful life.”

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<sup>24</sup> § 411.357(l).

<sup>25</sup> § 411.357(i).

Finally, CMS confirmed that a lessor may charge a holdover lessee a premium, provided that the premium was set forth in the lease agreement and the total payment is still consistent with FMV (and does not take into account the volume or value of referrals or other business generated between the parties). Although urged by a commenter, CMS declined to permit the holdover grace period to last for as long as a landlord is proceeding with eviction. As such, the holdover period remains six months.

**2. *Reed Smith Comments.*** While CMS did not make any changes to the lease exceptions, per se, the new Phase III rules regarding physicians “standing in the shoes” of their physician organizations (as discussed above in Section II.C.2.), impacts the application of these exceptions. In a nutshell, prior to Phase III, leasing arrangements between hospitals (or other DHS entities) and physician groups were treated as a potential indirect compensation arrangements, and, as such, the lease exceptions (which apply only to direct compensation arrangements) did not apply. However, given the stand in the shoes provisions of Phase III, many arrangements may need to be restructured to comply with the applicable lease exception (space or equipment). (Some arrangements may already be structured to comply (or substantially comply) with the anti-kickback law safe harbor for leases, but this may not be sufficient for Stark Law compliance.) Note, however, that leases between a DHS entity and a separate corporation or other entity owned by physicians may not meet the definition of “physician organization” under Phase III and would still be subject to analysis as an indirect compensation arrangement. Finally, as discussed above, Phase III does provide a grandfathering period for certain arrangements structured meet the exception for indirect compensation arrangements before September 5, 2007.

Moreover, we note that, in the 2008 MPFS Proposed Rule, CMS proposed to restructure the lease exceptions so that “per-click” (i.e., a per-use or per-service fee) lease payments, where the physician is the lessor, would no longer be permissible. Specifically, CMS proposed to add the following provision to the space and equipment lease exceptions:

Per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

This proposed change represents a reversal of CMS’s current regulatory position: although CMS originally would have prohibited such arrangements, CMS changed its mind in the final 2001 Phase I regulations and expressly stated that, in connection with space and equipment leases, it would permit “time-based or unit-of-service-based payments, even when the

physician receiving the payment has generated the payment through a DHS referral.”<sup>26</sup> CMS acknowledged that one reason it reached this conclusion was because the Stark Law’s legislative history showed that Congress intended to permit time-based and unit-of-service arrangements.<sup>27</sup> That said, in the 2008 MPFS Proposed Rule, CMS invoked its statutory authority to impose requirements to protect against fraud and abuse, and, in apparent contrast to legislative intent has recommended elimination of per-click payments under the circumstances outlined above. It is also important to recall that, at the time this change was proposed, it would have only applied to instances where an individual physician was the lessor. Now that CMS has adopted the “stand in the shoes” rule, the proposed restriction on per-click lease payments would appear to apply to arrangements where a physician group (or “physician organization”) is the lessor as well, and, in this way, is broader in potential application. Finally, we note that CMS, in the 2008 MPFS Proposed Rule, solicited comments regarding whether per-click payment should be prohibited where the DHS entity is the lessor, which would even further restrict the applicability of these exceptions.

#### **B. Bona Fide Employment Relationships**

CMS did not receive any comments regarding the exception for bona fide employment relationships,<sup>28</sup> and, as such, provided no responsive commentary. CMS did not make any changes to the exception either. It is worthy of note, however, that while CMS made changes to the method by which group practices may pay productivity bonuses, it did not make parallel changes to the employment exception. See discussion of productivity bonuses at Section III.A.

#### **C. Personal Service Arrangements**

1. ***Overview of CMS’s Comments/Changes.*** CMS made two changes to the personal services exception.<sup>29</sup> First, it added a provision permitting “holdover” personal services arrangements, for up to a period of six months after the expiration of an agreement of at least a year. Similar to the holdover provisions CMS added to the leasing exceptions in a prior version of the rules, the holdover period must be on the same terms and conditions as the immediately preceding agreement. Accordingly, if a personal services arrangement, such as a

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<sup>26</sup> 66 Fed. Reg. at 876.

<sup>27</sup> Id.

<sup>28</sup> § 411.357(c).

<sup>29</sup> § 411.357(d).

medical directorship, continues in effect after the written agreement has expired, the parties will not fall outside the personal services exception until six months have passed (provided the other requirements of the exception are satisfied).

Second, CMS modified the part of the personal services exception addressing physician incentive plans. In particular, CMS modified the text of the regulation to consistently refer to “downstream contractors,” for which it developed a new definition, instead of “subcontractors.” CMS explained that a “downstream contractor” includes both “an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items and services (that is, a first tier contractor) and an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision of or arrangement for items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor.” A “first tier contractor” is an individual or entity that contracts directly with a managed care organization to provide or arrange for items or services.

CMS also provided some insight into the application of the personal services exception, through its response to various comments. In particular, CMS explained that the component of the exception that requires the agreement to cover all of the services to be furnished by the physician (or her or her immediate family member) or group practice is a bright-line rule. Therefore, all services must be included in the agreement or master list of agreements, not just services that are similar to related to the services performed by the physician.

In addition, CMS noted that personal services contracts may be amended in the same manner as lease contracts (as discussed above in Section VI.A.1.).

**2. *Reed Smith Comments.*** As discussed above in connection with the exceptions for space and equipment leases, CMS’s adoption of the “stand in the shoes” rule impacts the application of the personal services exception. For example, while a contract between a hospital and a physician group for the provision of medical directorship services would have historically been analyzed to determine whether the arrangement gave rise to an indirect compensation arrangement, such an arrangement will now be viewed as a direct compensation arrangement. Therefore, the personal services exception will apply (instead of the exception for indirect compensation arrangements). That said, arrangements that have other intervening parties will still be analyzed under the definition of (and exception for) indirect compensation arrangements. CMS cites one example in the Phase III preamble: a hospital contracts with a medical foundation, which, in turn, contracts with a group practice that employs

physicians. While, under Phase III, the physician will stand in the shoes of the group practice, whether or not the hospital has a financial relationship with the group practice will turn on an analysis of the definition of an indirect compensation arrangement, as the foundation serves as an intervening entity. Referrals by the physician to the foundation, however, would still be analyzed as a direct compensation relationship, CMS notes.

**3. *Elimination of Safe Harbor for Hourly Payments.*** In addition to revising the personal services exception, CMS also made a significant change to the definition of “fair market value” that affects personal service arrangements that involve hourly compensation. Specifically, CMS deleted the existing safe harbor for hourly payments for a physician’s personal services that met certain community emergency room hourly rate averages or were set at the 50th percentile level in specified national physician compensation surveys. Reasons cited for the withdrawal of the safe harbor include:inconsistent availability of survey data

- expense of obtaining survey data
- difficulty in obtaining emergency room physicians’ rates at competitor hospitals

Although the safe harbor status of using these hourly fee benchmarks has been eliminated, CMS continues to urge DHS providers to refer to multiple, objective, independently published salary surveys in evaluating the fair market value level of payments to physicians for their services. CMS also reiterates that parties can calculate FMV by using any commercially reasonable methodology that is appropriate under the circumstances.

**4. *Reed Smith Comments.*** CMS’s stated reasons for withdrawing the hourly payment safe harbor reflect complaints we have heard repeatedly for several years. Accordingly, many entities have found themselves already using other commercially reasonable methods for determining FMV payment rates. CMS raises a fair question of whether payment rates to physicians for both administrative and clinical work should differ from one another. In all cases, DHS entities should ensure that their payments to physicians are for necessary, documented work and that the FMV level of payment can be documented and defended based on commercially reasonable, objective information for the community and the type of work performed.

#### **D. Physician Recruitment**

Stark II contains an exception that allows a hospital to furnish remuneration to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. Under this exception, the physician cannot be required to refer patients to the hospital, the amount of remuneration cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the recruited physician; and the arrangement must meet any other requirements imposed by the Secretary to protect against program or patient abuse.

Phase II established several clarifications and modifications to this exception. Specifically, Phase II provided that a recruited physician must relocate his medical office, rather than his residence, must be new to the hospital's medical staff and must relocate to the geographic area served by the hospital (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients). In addition, the recruited physician must either relocate his office a minimum of 25 miles or derive at least 75 percent of his revenues from services provided to new patients. Phase II did not impose the relocation requirements upon recruited physicians who are residents or physicians who have been in medical practice less than 1 year. In Phase II, CMS expanded the exception to include recruitment by federally qualified health centers on the same basis as hospitals. Finally, Phase II allowed recruitment payments to be made through existing group practices (rather than directly to the recruited physician) under limited circumstances aimed at ensuring that any remuneration is for the benefit of the recruited physician and does not inure to the benefit of the existing physicians in the group.

Phase III makes numerous additional changes to the physician recruitment exception, and the Phase III Preamble provides additional guidance on the application of the exception. The most significant changes relate to recruitment through existing group practices, relaxation of certain aspects of the requirement that the recruited physician must relocate to the hospital's geographic area, and expansion of the exception to recruitment by rural health clinics. The first two areas of change are described below.

1. ***Recruitment through Existing Medical Practices.*** Phase II specifically allowed hospitals to support physician recruitment through existing medical practices, but imposed several limitations on such arrangements, including requirements that: the written recruitment agreement must also be signed by the medical practice; except for actual costs

incurred by the medical practice in recruiting the new physician, the remuneration must be passed directly through to the recruited physician; in the case of an income guarantee made by the hospital to a recruited physician who joins medical practice, the costs allocated to the recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician; records of the actual costs and the passed-through amounts must be maintained for a period of at least 5 years and made available to the Secretary upon request; the remuneration from the hospital may not be determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the recruited physician or the medical practice (or its physicians); the medical practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care; and the arrangement may not violate the anti-kickback statute or certain other federal or state laws.

Among the most controversial aspects of Phase II was the limitation on the imposition of “additional practice restrictions” by medical practices through which a hospital conducts recruitment. Hospitals were concerned that joint recruitment with a medical practice would often be the most effective and efficient means to recruit a new physician, but that a medical practice that could not impose a noncompetition agreement on the recruited physician would not participate in joint recruitment efforts. In Phase III, CMS explicitly permits practice restrictions that do not “unreasonably restrict the recruited physician’s ability to practice medicine in the geographic area served by the hospital.” As explained in the Preamble, this would not preclude a medical practice from requiring a recruited physician to enter into a post-employment noncompetition agreement. Thus, for example, if the radius of the practice restriction on the recruited physician is reasonable to protect the business of the medical practice and would not unreasonably prevent the recruited physician from practicing elsewhere in the hospital’s service area, a noncompetition agreement is now permissible. Similarly, CMS indicated in the preamble that several other types of restrictive covenants (e.g., restrictions on moonlighting, prohibitions on soliciting patients and/or employees, requiring that the recruited physician treat Medicaid and indigent patients, requiring that a recruited physician not use confidential or proprietary information of the medical practice and requiring the recruited physician to repay losses that are absorbed by the medical practice in excess of any hospital recruitment payments) would not violate the exception. In addition, CMS indicated that a requirement upon the recruited physician to pay liquidated damages if the physician leaves the medical practice and remains in the community would not violate the exception if the payment is not so significant or unreasonable as to have a substantial effect on the recruited physician’s ability to remain in the hospital’s service area.

In Phase III, CMS also addresses the limitation on a hospital's payment of actual additional incremental costs attributable to the recruited physician. First, CMS clarifies that this limitation applies to "any type of income guarantee," including for example gross income, net income, and revenue formulas. Second, CMS clarifies that certain of a medical practice's costs, such as headhunter fees and expenses associated with visits to the area by the recruited physician, can be reimbursed by the hospital, but that the value of the time spent by physicians in the medical practice is not covered by the exception. Most significantly, CMS relaxed the incremental cost limitation for rural hospitals that recruit a physician to join a medical practice located in a rural area or health professional shortage area ("HPSA") if the recruited physician is a replacement for a physician who has retired, relocated outside of the geographic area served by the hospital, or died. In such a case, the hospital's remuneration to the medical practice may be as much as the lower of a per capita allocation of the medical practice's expenses to the recruited physician or 20 percent of the practice's aggregate costs.

CMS provides interesting commentary concerning the imposition of a requirement by a hospital that a medical practice guarantee any repayment obligations of the recruited physician to the hospital. Recruitment arrangements are often structured as loans of funds to subsidize the income of the recruited physician during the early years following the physician's relocation, with the repayment obligation forgiven over several additional years if the physician remains in the hospital's service area. Nothing in Stark II or Phase III requires this structure, including the imposition of any repayment obligation from the recruited physician, however. Responding to a comment, CMS states that Stark II does not preclude a medical practice's guarantee of a recruited physician's repayment obligation, but cautions that the use of such a guarantee to shield the recruited physician from liability to honor his community service obligation could put the parties at "significant risk of noncompliance with the fraud and abuse laws," particularly if the hospital fails to collect amounts owed by the medical practice under the guarantee. Additionally, CMS warns that such a guarantee could create financial relationships between the medical practice and the recruited physician and the medical practice and the hospital that could implicate fraud and abuse laws, including Stark II and the anti-kickback statute.

**2. *Relocation to the Hospital's Geographic Area.*** As indicated above, Phase II had defined the geographic area served by the hospital (that is, the area into which a recruited physician must relocate his office) as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients. In Phase III, CMS makes certain changes to respond to public comments suggesting that this definition is unworkable or



too narrow in certain circumstances. For a hospital for which no combination of contiguous zip codes represent at least 75 percent of the hospital's inpatients, the hospital's geographic service area can now encompass all of the contiguous zip codes from which the hospital's inpatients are drawn. Further, CMS creates an alternative definition for rural hospitals that allows physician relocation to a broader geographic area. Specifically, for a hospital located in a rural area, the geographic area is that composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If such a hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the hospital may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients. CMS clarifies that, where more than one configuration of zip codes satisfies the 75 percent or 90 percent tests, the hospital can use any of the configurations, and that the test is applied as of the date that the recruitment agreements are signed (even though the application of the test may change thereafter). Also, hospitals and federally qualified health centers that are located in rural areas and rural health clinics may be able to obtain an advisory opinion that expands their geographic areas to permit recruitment to other areas of demonstrated need.

As indicated above, under Phase II, the relocation requirements did not apply to residents and physicians in practice for less than one year. In Phase III, CMS expands the exception to the relocation requirement to include physicians who were employed during the preceding two years on a full-time basis by a federal or state bureau of prisons or similar entity to serve exclusively a prison population, the Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families, or facilities of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service. In each such case, the physician must not have maintained an independent private practice in addition to his or her fulltime employment. Additionally, Phase III allows for hospitals to identify other classifications of physicians to be exempt from the relocation requirements through the advisory opinion process.

#### **E. Isolated Transactions**

Isolated transactions, such as such as a one-time sale of property or a medical practice, are covered by an exception under Stark II if the amount of remuneration is consistent with fair market value and is not determined, directly or indirectly, in a manner that takes into account the volume or value of referrals, and the remuneration is provided in accordance with an agreement

that would be commercially reasonable even if no referrals were made to the entity. In Phase II, CMS established additional guidance on this exception. Specifically, Phase II required that there be no additional transactions between the parties for six months after the isolated transaction, except for transactions that meet other exceptions, and provided that installment payments could qualify as isolated transactions if the total aggregate payment is set before the first payment is made and does not take into account, directly or indirectly, referrals or other business generated by the referring physician. Additionally, under Phase II, the installment payments must be immediately negotiable or guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party. Finally, Phase II clarified that post-closing adjustments that are commercially reasonable and not dependent on referrals or other business generated by the referring physician are permitted if made within six months after the date of the transaction.

In Phase III, CMS makes no changes to the isolated transactions exception. In the Preamble, however, CMS does clarify certain aspects of this exception. First, in response to a commenter's question about the requirement to secure installment payments, CMS states that a negotiable promissory note evidencing the installment payment obligations is sufficient to satisfy this requirement, and that the note's negotiability is governed by state law (such as the UCC). Second, CMS clarifies that, since the exception permits commercially reasonable post-closing adjustments only during the first six months following the transaction, any post-closing adjustments thereafter would be treated as a separate, additional transaction that would need to meet the requirements of an exception, and that claims based on breach of a warranty are not considered post-closing adjustments but rather part of the original transaction and therefore may take place at any time. CMS also explains that a guaranty by a DHS entity does not create an ownership interest in the entity providing the guaranty (although it may constitute a compensation arrangement).

#### **F. Remuneration Unrelated to DHS**

Stark II includes an exception for remuneration provided by a hospital to a physician that does not relate to the furnishing of DHS. In Phase II, CMS substantially narrowed this exception by interpreting it to apply only if the remuneration is *wholly* unrelated to the provision of DHS. CMS went on to provide that any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles is considered to be related directly or indirectly to the provision of DHS, and that remuneration is considered related to DHS for purposes of this exception if it is furnished, directly or indirectly, explicitly or

implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other physicians in a position to make or influence referrals.

CMS makes no changes to this exception in Phase III. In the Preamble, CMS disagrees with commenters who asserted that CMS's Phase II interpretation is inconsistent with statutory language and congressional intent. Other than waiving an entry fee for all participants (that is, not just members of the medical staff) in a hospital's charity golf outing, CMS identified no other arrangements that would fall within this exception. Despite a commenter's concern, CMS acknowledges that this exception would not provide a basis for a hospital to provide malpractice insurance assistance to physicians.

**G. Payments by a Physician**

Under Stark II, an exception exists for certain payments that a physician makes to a laboratory in exchange for clinical laboratory services or to an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value. Phase II extended this exception to payments by immediate family members, but limited its applicability to circumstances where no other Stark II exception is available. Despite commenters' concerns that this exception can only be used as a "last resort" when no other exception is applicable, CMS does not change this exception in Phase III.

While the rental of office space and equipment exceptions contemplate payments *to* or *from* a physician, many other exceptions, such as the personal services arrangements exception and the fair market value exception, have provided protection only for payments made *to* a physician. Thus, historically, the "payments by a physician" exception has been available and important for many non-lease arrangements. In Phase III, as discussed elsewhere, CMS is revising the fair market value exception to cover also payments *by* a physician. As a result, most non-lease arrangements that previously could not possibly qualify for the fair market value exception now could potentially qualify and, thus, will need to be structured (or restructured) to satisfy all of the requirements of that exception rather than the payments-by-a-physician exception. The end result is that the payments-by-a-physician exception will hereafter largely be meaningless since it will only be available when no other exception could potentially apply.

## **H. Charitable Donations by a Physician**

In Phase II, CMS created a regulatory exception for bona fide charitable donations made by a physician (or his or her immediate family member) to an entity furnishing DHS if: (1) the entity is an organization exempt from taxation under the Internal Revenue Code (or to an exempt supporting organization, such as a hospital foundation), (2) the donation is not solicited or made in any manner that reflects the volume or value of referrals or other business generated between the parties, and (3) the arrangement does not violate the anti-kickback statute or billing or claims submission rules.

A commenter was concerned that a hospital could be at risk for a donating physician's conduct because, while a hospital recipient can control how it solicits donations, it cannot control whether or not a physician makes a donation in a manner related to referrals. In response, in Phase III, CMS is amending the exception to provide that the entity may not solicit the donation, nor may the physician offer the donation, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity.

## **I. Nonmonetary Compensation**

**1. *Expansion & Opportunity to Cure.*** The non-monetary compensation exception protects nonmonetary compensation (such as gifts, meals, entertainment, etc.) provided to referring physicians up to \$300 per year (adjusted annually for inflation according to the CPI-U) in specified circumstances.<sup>30</sup> Phase III has expanded the exception in order to protect certain nonmonetary compensation in excess of the \$300 limit (\$329 in CY 2007 accounting for inflation) from violating the exception.

Specifically, nonmonetary compensation in excess of the limit will no longer violate the exception so long as its value is no greater than 50 percent of the limit, and the physician repays the excess, either before the end of the calendar year in which the physician received it or 180 days from the date the physician received it (whichever is earlier). The frequency with which the parties may rely on this cure for excess nonmonetary compensation is limited to once every three years per referring physician.

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<sup>30</sup> § 411.357(k).

In response to comments, CMS clarified that remuneration provided to referring physicians by a parent company of multiple DHS entities is not subject to the nonmonetary compensation limit (which only applies to each individual DHS entity), but that such remuneration could create an indirect compensation arrangement.

**2. *Medical Staff Appreciation Event.*** CMS has determined that the value of an annual “medical staff appreciation event” is exempt from the nonmonetary compensation limit because it does not create a risk of abuse. To qualify for the exemption, the medical staff appreciation event must be held locally and open to all medical practitioners in the entity’s formal medical staff. Any “gifts or gratuities” provided, however, will continue to be subject to the nonmonetary compensation limit.

**3. *Reed Smith Comments.*** The cure for correcting the provision of excess nonmonetary compensation may be less useful in practice than it initially seems. It contemplates excesses that are both minor and inadvertent and that are discovered before the physician repayment deadlines (the end of the calendar year or within 180 days of receipt). It does not protect inadvertent excesses that are never discovered or that are not discovered until too late, which may be the case in the majority of inadvertent violations. Further, the frequency limitation is significant. Although CMS states that referrals made after a physician’s receipt of non-monetary compensation that meets this exception do not violate Stark, CMS recommends a suspension of billing between the time of discovery and the physician’s repayment of the non-monetary compensation.

## **J. Fair Market Value Compensation**

The fair market value (or FMV) compensation exception protects compensation paid to a referring physician (a member of his/her immediate family, or physician group) so long as it meets certain conditions as set forth in § 411.357(l). In Phase III, CMS has revised the exception to expressly exclude leases for office space (which it does not believe is an “item or service” for the purposes of this exception)<sup>31</sup> and to make clear that the exception applies equally to compensation paid by a referring physician to a DHS entity and to compensation paid by a DHS entity to a referring physician.

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<sup>31</sup> 72 Fed. Reg. at 51059.

These changes are designed to address the overlap between various compensation arrangement exceptions and prevent physicians and DHS entities from being able to comply with the less restrictive exception. For example, the exclusion of office space lease arrangements from the FMV exception is intended to prevent entities and physicians from relying on this exception instead of complying with the more restrictive “rental of office space exception” set forth in § 411.357(a). Further, because the “payments by a physician” exception in § 411.357(i) only applies to arrangements “that are not specifically addressed by another [exception] including but not limited to [subsection (l)],” the clarification with respect to compensation paid by a physician to a DHS entity could often preclude the parties from relying on subsection (i). Accordingly, all office-space lease arrangements and physician compensation arrangements in which the compensation is paid to the DHS entity by the physician should be reviewed prior to the effective date to ensure compliance with the exceptions for office space rental or payments by a physician rather than with the FMV exception.

CMS declined to elaborate on what constitutes FMV or to establish a rebuttable presumption that all transactions are FMV, emphasizing that “[i]f questioned by the government, the burden would be on the parties to explain how the transaction meets the fair market value compensation exception requirements.”<sup>32</sup> Therefore, it remains important to review and document all compensation transactions that rely on this exception for consistency with FMV as defined in § 411.351.

**K. Medical Staff Incidental Benefits**

This exception protects certain non-cash (or cash equivalent) compensation provided by a hospital to its bona fide medical staff that is incidental to the services being provided by the medical staff at the hospital and whose value is less than \$25 dollars per item/service (for example, parking or cafeteria meals) adjusted annually for inflation.<sup>33</sup> CMS has not made any substantive changes to this exception in Phase III. However, in response to a comment, CMS indicated that a hospital’s referral service may either meet the medical staff incidental benefits exception or the referral services exception set forth at § 411.357(q) (which requires compliance with the referral services safe harbor in § 1001.952(f)) if all the conditions of the exception are satisfied.

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<sup>32</sup> 72 Fed. Reg. at 51,060.

<sup>33</sup> § 411.357(m),

**L. Compliance Training**

Prior to Phase III, to be eligible for this exception, compliance training could not provide continuing medical education (“CME”) credit. CMS has eliminated this restriction such that compliance training can provide CME credit on the condition that compliance training “predominates” or remains the “primary purpose.” CMS recognizes that, practically speaking, whether or not a compliance training program offers CME credit should not determine whether it complies with this exception. CMS cautions, however, that “[t]he revised exception does not protect traditional CME content under the guise of ‘compliance training.’”<sup>34</sup>

**M. Indirect Compensation Arrangements**

Although CMS has made no substantive changes to the indirect compensation exception, the changes discussed above in Section II.C.2. with respect to how direct and indirect compensation arrangements are defined and the addition of the “stand in the shoes” concept will have the effect of limiting the applicability of this exception by turning many indirect compensation arrangements into direct compensation arrangements, ineligible for this exception.

Although the applicability of this exception will be narrowed, CMS provided examples of arrangements that will still meet the definition of an indirect compensation arrangement even after applying the “stand in the shoes” provision. For instance, one commenter posed a hypothetical in which a hospital contracts for outpatient radiology with a joint venture owned by the hospital and physicians (with payment based on a percentage of the hospital’s collections). CMS stated that this scenario involves two indirect compensation arrangements, each of which must meet the indirect compensation exception: the joint venture relationship between the hospital and the physicians, and the ownership interest (that does not meet an ownership exception and is thus a compensation arrangement) from the hospital to the radiology venture to the physicians.

**N. Obstetrical Malpractice Insurance Subsidies**

CMS made no substantive changes to the obstetrical malpractice insurance exception.<sup>35</sup> In response to comments, CMS stated that DHS entities may provide assistance

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<sup>34</sup> 72 Fed. Reg. at 51,061.

<sup>35</sup> § 411.357(r).

with malpractice insurance pursuant to a number of exceptions, including the FMV compensation exception, the exception for *bona fide* employment relationships, and the personal service arrangements exception. We note, however, that as discussed in our memorandum on the 2008 MPFS Proposed Rule, CMS is seeking comments as to whether it should broaden the application of the exception due to anecdotal reports it received of obstetricians being forced to leave certain states for other practice locations.

**O. Professional Courtesy**

CMS clarified two aspects of the professional courtesy exception.<sup>36</sup> First it clarified that the exception is only intended to apply to providers with a formal medical staff (such as a hospital). Second, CMS amended the language slightly to clarify that the entity's governing body must approve its written professional courtesy policy before such an arrangement can meet this exception.

CMS also eliminated the requirement that the insurer be notified where the professional courtesy results in any reduction of a coinsurance obligation. CMS believes that this practice is "prudent" and notes that insurers may have their own requirements with respect to this practice, but acknowledges that the requirement does nothing to reduce the risk of program abuse.

**P. Retention Payments in Underserved Areas**

This exception was developed to allow underserved hospitals to offer a retention payment when a physician is offered a more lucrative position in another area and to guard against physician shortages.<sup>37</sup> However, according to the comments, the requirements of this exception limit its scope and utility. CMS responded by broadening the exception in several ways.

First, prior to Phase III, this exception only applied to hospitals and only to situations in which the potential employer of the retained physician was also a hospital. CMS expanded the exception to apply to rural health clinics and federally qualified health centers, as well as hospitals. Further, the exception will now apply to situations in which potential

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<sup>36</sup> § 411.357(s).

<sup>37</sup> § 411.357(t).



employer is an academic medical center or physician organization (so long as it is unrelated to the provider offering the retention payment).

Second, the physician's current medical practice no longer has to be located in a HPSA to meet this exception. Instead, either the physician's current medical practice must be in an HPSA (or a rural area, or an area of "demonstrated need as determined by the Secretary in an advisory opinion"), or 75 percent of the physician's current patients must either reside in a medically underserved area or be members of a medically underserved population.

Finally, CMS revised the exception to allow the provider to offer retention payments, even where the physician does not have a written offer of employment from another provider. In the alternative, CMS will require the physician to certify in writing certain facts, including the existence of a *bona fide* offer of employment that would require relocation to another area, details regarding the opportunity (such as anticipated income, etc.), and that the potential employer is not related to the current employer/provider, among other things. In cases where the provider obtains the physician's written certification (rather than a written offer of employment from the potential employer), CMS provides alternate limits on the permissible amount of the retention payment. Specifically, where the provider is relying on the physician's written certification, the payment can not exceed 25 percent of the physician's current annual income (based on the preceding 24 months), or the reasonable estimated cost of recruiting a physician with similar qualifications and experience to replace the retained physician, (whichever is less).

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Please contact Kevin R. Barry (202/414-9211, [kbarry@reedsmith.com](mailto:kbarry@reedsmith.com)); Gina M. Cavalier (202/414-9288, [gcavalier@reedsmith.com](mailto:gcavalier@reedsmith.com)); Katie A. Durkin (202/414-9299; [cdurkin@reedsmith.com](mailto:cdurkin@reedsmith.com)); Thomas W. Greeson (703/641-4242; [tgreeson@reedsmith.com](mailto:tgreeson@reedsmith.com)); Paul Pitts (415/659-5971; [ppitts@reedsmith.com](mailto:ppitts@reedsmith.com)); Karl A. Thallner, Jr. (215/851-8171, [kthallner@reedsmith.com](mailto:kthallner@reedsmith.com)); Heather M. Zimmerman (202/414-9341, [hzimmerman@reedsmith.com](mailto:hzimmerman@reedsmith.com), or any other member of the Reed Smith health care group with whom you work if you would like additional information or if you have any questions.

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