

2001 HEALTH LAW UPDATE

HONIGMAN MILLER SCHWARTZ AND COHN LLP

Stark II Phase I Final Regulations

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Honigman Miller Schwartz and Cohn LLP
2001 Health Law Update: STARK II PHASE I FINAL REGULATIONS

By Gerald M. Griffith, Carey F. Kalmowitz and Patrick LePine.¹

The purpose of this article is to alert readers to key points of the Phase I portion of the final Stark II regulations (the "**Phase I Final Regulations**") issued by the Health Care Financing Administration ("**HCFA**") and published on January 4, 2001.² This article is intended to provide general information rather than advice as to any specific type of transaction or relationship. Anyone with questions concerning a particular transaction or relationship is urged to discuss those questions with experienced legal counsel.

A. OVERVIEW OF THE STARK LAW

The Stark Law³ generally prohibits a physician from making referrals for the furnishing of designated health services ("**DHS**"),⁴ for which payment may be made under the Medicare or Medicaid programs, to any entity with which the physician or immediate family member has a financial relationship. Financial relationships include any direct or indirect compensation arrangement with an entity for payment of any remuneration, and any direct or indirect ownership or investment interest in the entity whether, by debt, equity or otherwise. If a financial relationship exists, regardless of intent, the physician is precluded from referring patients to the entity for DHS and the entity that furnishes DHS (the "**DHS entity**") is precluded from billing Medicare and Medicaid for any such referred services, unless the arrangement meets a statutory exception. The exceptions for these financial relationships⁵ fall into three general categories: exceptions applicable to both compensation and ownership/investment arrangements, exceptions applicable only to ownership or investment arrangements and exceptions applicable only to compensation arrangements. There is no intent requirement for Stark Law violations⁶ and a violation could subject any provider to various penalties, including civil money penalties and exclusion from the Medicare and Medicaid programs.

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² 66 Fed. Reg. 856 (Jan. 4, 2001).

³ Section 1877 of the Social Security Act (the "**Act**").

⁴ "Designated health services" are defined in the Stark Law to include the following services: clinical laboratory services; physical therapy ("**PT**") services; occupational therapy ("**OT**") services; radiology services including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment ("**DME**") and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 U.S.C. §1395nn(h)(6).

⁵ With respect to exceptions, for example, the Phase I Final Regulations focus solely on the rule covering exceptions applicable to ownership/investment interests and compensation arrangements: 42 C.F.R. §§411.355, 411.357, although several additional exceptions are added to the rule governing exceptions for compensation arrangements. It is expected that Phase II will address the exceptions for compensation arrangements and ownership/investment interests 42 C.F.R. §§411.356-57.

⁶ The Phase I Final Regulations, however, impose a "knowledge" requirement to establish both an indirect compensation arrangement and an indirect ownership or investment interest.

B. SCOPE OF THE PHASE I FINAL REGULATIONS AND COMMENT PERIOD

The Phase I Final Regulations comprise the first of two phases of HCFA's rulemaking to implement the terms of the Stark Law. The Phase I Final Regulations have a 90-day comment period and focus on those paragraphs of the Stark Law setting forth (i) the statute's general prohibition, (ii) the exceptions pertaining to both ownership and compensation relationships, and (iii) definitions that are used throughout the Stark Law. The Phase I Final Regulations become effective on January 4, 2002 (except for the rulemaking addressing referrals to home health, which was due to have become effective on February 5, 2001).⁷ HCFA iterated that until the effective date of the Phase I Final Regulations, the August 1995 final rule covering referrals for clinical laboratory services (the "**Stark I Final Rules**") remains in full force and effect with respect to clinical laboratory services referrals and claims for services.

According to the preamble, Phase II of the final rulemaking (the "**Phase II Final Regulations**") will address the remaining sections of the Stark Law and, in addition, will reflect further changes to the final rules based on the comments that HCFA receives on these Phase I Final Regulations. Although HCFA notes that it intends to publish the Phase II Final Regulations "shortly," the fact that the Phase II Final Regulations will incorporate the agency's response to comments on the Phase I Final Regulations suggests that there might be an appreciable hiatus before the Phase II Final Regulations are released.

C. KEY CHANGES IN PHASE I FINAL REGULATIONS

In a number of respects, the Phase I Final Regulations differ substantially from the January 1998 Proposed Regulations (the "**Proposed Regulations**").⁸ These changes, each of which is discussed in greater detail in this article, generally fall into one of three principal areas:

1. Definitional Clarifications

- (i) clarifying the definitions of DHS;
- (i) clarifying the concept of "indirect financial relationship";
- (iii) interpreting the "volume or value" standard to permit unit of service or unit of time-based payments, so long as the unit of service or unit of time-based payment is fair market value and does not vary over time; and
- (iv) exclusion of services personally performed by the referring physician from the definition of "referral."

2. Expansion Of The In-Office Ancillary Services Exception

- (i) relaxing the criteria for qualifying as a "group practice" and conforming the supervision requirements to HCFA coverage and payment policies for the specific

⁷ The effective date of home health provisions of the Phase I Final Regulations 42 C.F.R. 424.22 is pending pursuant to the 60-day delay imposed on certain federal regulations published prior to, but not effective as of, January 20, 2001.

⁸ 63 Fed. Reg. 1659 (Jan. 9, 1998).

- services;
- (ii) covering certain DME provided in physicians' offices to patients to assist them in ambulating, as well as blood glucose monitors; and
- (iii) allowing shared facilities in the same building where physicians routinely provide services in addition to DHS.

3. Creation of New Exceptions

- (i) for compensating faculty in academic medical centers;
- (ii) for indirect compensation arrangements;
- (iii) for "risk-sharing" arrangements involving commercial and employer-sponsored managed care plans; and
- (iv) where DHS are furnished by entities that did not know of or have reason to suspect the identity of the referring physician.

D. REFERRAL PROHIBITION

Since its inception, the hallmark of the Stark Law that distinguished it from the Medicare and Medicaid Anti-kickback Statute (the "**Anti-kickback Statute**")⁹ was the absence of an intent requirement for the Stark Law (short of special circumstances for proving a "circumvention scheme" under Section 1877(g)(4) of the Act).¹⁰ In the Phase I Final Regulations, HCFA included a limited exception to permit payment of claims for DHS referred in a manner that does not conform with the Stark Law so long as (i) the entity submitting the claim "did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity"; and (ii) the claim otherwise complies with applicable federal law, rules and regulations.¹¹ This exception is limited to situations where the entity does not know the source of the referral. It does not cover situations where the entity (in the broad institutional sense) knows the source of the referral but does not know that the physician's financial relationship with the entity fails to meet a Stark Law exception. The practical effect of this exception may be to reduce the likelihood of successful False Claims Act (or "qui tam") lawsuits based on inadvertent violations.

The Phase I Final Regulations provide two further significant modifications to limit the scope of the prohibition. First, when a physician refers to himself/herself, that act does not constitute a referral to an "entity" for purposes of the Stark Law. In addition, a physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to the group practice or its members or staff; however, referrals made by the group practice, members or staff may be imputed to the physician if he or she directs the referral to be made or otherwise controls referrals they make.¹²

⁹ 42 U.S.C. §1320a-7b(b).

¹⁰ 42 U.S.C. §1395nn(g)(4).

¹¹ 42 C.F.R. §411.353(a); 66 Fed. Reg. at 958.

¹² 42 C.F.R. §411.353(a); 66 Fed. Reg. at 958.

E. DEFINITIONS/GENERAL CONCEPTS

Although C.F.R. §411.351, the definitional provision in the Phase I Final Regulations, provides definitions of approximately thirty terms used in the rule,¹³ this article will focus on the definitions for to which HCFA's clarification or revision were most significant.

1. Designated Health Services

1.1. Definition of "Designated Health Services"("DHS"). With certain limited differences (discussed below), the list of services comprising "designated health services" ("DHS") in the Phase I Final Regulations is consistent with the Proposed Regulations' definition. Under the Phase I Final Regulations, the following constitute DHS: (1) clinical laboratory services; (2) PT services, OT and speech-language pathology services; (3) radiology and certain other imaging services; (4) radiation services and supplies; (5) DME and supplies; (6) parenteral and enteral nutrients, equipment, and supplies; (7) prosthetics, orthotics, and prosthetic devices and supplies; (8) home health services; (9) outpatient prescription drugs; and (10) inpatient and outpatient hospital services.¹⁴ Unless otherwise specifically noted in the Phase I Final Regulations,¹⁵ for purposes of the Stark Law, the term "designated health services" mean only DHS that are payable, in whole or in part, by Medicare.¹⁶

Whereas neither the statute nor the Proposed Regulations provide certainty as to whether specific services constitute DHS for purposes of the Stark Law, the Phase I Final Regulations define certain services (clinical laboratory services, PT, OT, radiology and certain other imaging services, and radiation therapy services)¹⁷ by reference to specific lists of Current Procedural Terminology ("CPT") and HCFA Common Procedure Coding System ("HCPCS") codes included on the *List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions* (Section 1877 of the Social Security Act) (the "**CPT/HCPCS List**"). The initial CPT/HCPCS List is set forth in an attachment to the Phase I Final Regulations (and posted on the HCFA website).¹⁸ Thereafter, the CPT/HCPCS List will be updated annually in an addendum to the physician fee schedule (and on the HCFA website). In

¹³ The following terms are defined: Centralized building; Clinical laboratory services; Consultation; Designated health services; DME; Employee; Entity; Fair market value; General market value; Home health services; Hospital; HPSA; Immediate family member or member of a physician's immediate family; "Incident to" services; Inpatient hospital services; Laboratory; CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act); Member of the group; Outpatient hospital services; Outpatient prescription drugs; Parenteral and enteral nutrients, equipment, and supplies; Patient care services; Physical Therapy, Occupational Therapy, and speech-language pathology services; Physician; Physician in the group practice; Physician incentive plan; Plan of care; Prosthetics, Orthotics, and Prosthetic Devices and Supplies; Radiation therapy services and supplies; Radiology and certain other imaging services; and Same building.

¹⁴ 66 Fed. Reg. at 953.

¹⁵ 42 C.F.R. §411.352(i)(2) (distribution of overall profits by a group practice); 42 C.F.R. §411.352(i)(3) (productivity bonus for personally performed services by a group practice); 42 C.F.R. §411.354(d)(3) (definition of "other business generated between the parties"); 42 C.F.R. §411.355(b)(2) (location requirement for in-office ancillary services exception).

¹⁶ 66 Fed. Reg. at 953.

¹⁷ Sections 1877(h)(6)(A) through (h)(6)(E) of the Act.

¹⁸ <http://www.hcfa.gov>.

all cases, the published list of codes will be controlling as to DHS falling within the purview of the Stark Law. Thus, with respect to the above-referenced categories of DHS, the Phase I Final Regulations afford providers the opportunity to determine whether a referral by a physician for a particular service falls within the scope of the Stark Law. The CPT/HCPCS List, however, do not cover the following categories of DHS: DME and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; or inpatient and outpatient hospital services.¹⁹

In the preamble to the Proposed Regulations, HCFA stated its belief that Congress intended that specific services should be included or excluded from the definition of DHS based upon whether the service potentially could be subject to abuse.²⁰ In the Phase I Final Regulations, however, HCFA modified its construction of congressional intent and determined that Congress did not intend to categorize DHS on the basis of the particular service's potential for overutilization or abuse. The practical effect is that, whereas in the Proposed Regulations, HCFA indicated its intent "to deviate from standard Medicare or Medicaid definitions of certain services in order to meet the intent of the statute,"²¹ the classifications in the Phase I Final Regulations are intended to conform with the general categories of DHS (*i.e.*, to be consistent with Medicare's classification of the service for purposes unrelated to the Stark Law).²² In other words, HCFA did not evaluate services individually to ascertain each service's susceptibility to abuse or overutilization with a view towards excluding those services where the potential for abuse/overutilization was considered limited from the list of DHS in the Phase I Final Regulations. Instead, the Phase I Final Regulations establish certain new limited exceptions under 42 C.F.R. §411.355 (*i.e.*, exceptions related to both ownership/investment and compensation) to cover a few specific cases where HCFA determined that an exception "poses a limited risk of abuse and is necessary to avoid needless disruption of patient care."²³ These exceptions (*i.e.*, relating to implants in ambulatory surgical centers ("**ASCs**"), legislatively mandated preventive screening tests and immunizations subject to frequency limits, eyeglasses and contact lenses subject to frequency limits, and erythropoietin ("**EPO**") provided by end-stage renal disease ("**ESRD**") facilities) are discussed further in Section I.4 below.

The Phase I Final Regulations also alter the coverage of DHS bundled within another service category. In the preamble to the Proposed Regulations, HCFA offered the example of PT or clinical laboratory services furnished by a skilled nursing facility ("**SNF**") and noted that, although most services furnished by a SNF are considered SNF services (which do not constitute DHS), the PT or clinical laboratory services rendered as part of the SNF services nonetheless still would be considered DHS.²⁴ Under the Phase I Final Regulations, by contrast, services that would otherwise constitute DHS, but that are paid by Medicare as part of a composite payment for a group of services as a separate benefit category (*e.g.*, services that are paid at the ASC rate),

¹⁹ Sections 1877(h)(6)(F) through (h)(6)(K) of the Act.

²⁰ This is illustrated by the following: "Because we believe that Congress meant to include under designated health services specific services that are or potentially could be subject to abuse, we are proposing to define those services accordingly." 63 Fed. Reg. at 1673.

²¹ 63 Fed. Reg. at 1673.

²² 66 Fed. Reg. at 922.

²³ 66 Fed. Reg. at 923.

²⁴ 63 Fed. Reg. at 1673.

are not DHS for purposes of the Stark Law.²⁵ Thus, under the example cited above from the Proposed Regulations, the PT or clinical laboratory services rendered by the SNF and paid at the composite SNF rate would be excluded from the definition of DHS, under the Phase I Final Regulations. In light of the SNF consolidated billing requirement, however, SNFs generally will be considered DHS entities for purposes of the Stark Law.²⁶ This principle does not apply, however, if the services that, by themselves, constitute DHS (*e.g.*, PT) are paid through a composite rate as part of a benefit category that itself constitutes DHS (*e.g.*, inpatient hospital services, outpatient hospital services and home health services).²⁷ That is, the fact that a particular service is bundled within a service category that is reimbursed through a composite rate does not necessarily mean that it will be excluded from the definition of DHS. Rather, such a service will be excluded only if the service category (within which such service is bundled) is not itself included on the list of DHS.

Further, to the extent that the CPT or HCPCS code for a particular service that is covered by the CPT/HCPCS List (*i.e.*, a DHS) includes a professional as well as a technical component, the professional component also will constitute a DHS. In other words, DHS are deemed to include the professional components when a professional component is included in the CPT or HCPCS codes that represent the particular service.²⁸ As noted in the commentary, the practical effect of including the professional component of many services within the definition of DHS is mitigated by the fact that, if the physician "personally performs" the service, the service nonetheless will not constitute a "referral"²⁹ for purposes of the Stark Law.³⁰

1.2. Radiology and Certain Other Imaging Services. The Proposed Regulations combined "radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services"³¹ and "radiation therapy services and supplies"³² into one category, "radiology services and radiation therapy and supplies."³³ Consistent with the

²⁵ 66 Fed. Reg. at 953. See commentary at 66 Fed. Reg. at 923.

²⁶ HCFA notes in the commentary that because of SNF consolidated billing (which charges the SNF with Medicare billing responsibility for most of the services that an SNF resident receives under Part A and under Part B), most, if not all, SNFs will also be considered entities providing DHS (for example, PT) under Part B to SNF patients who have exhausted their Part A benefit or to other nursing home residents (*i.e.*, patients for whom the services are not covered as part of a composite rate). Thus, absent meeting an applicable exception, a physician will *not* be able to refer Medicare patients who will require DHS to a SNF in which that referring physician has an ownership or investment interest. 66 Fed. Reg. at 953. To clarify, consolidated billing is a process for submitting claims, while composite rate payment constitutes a distinct payment methodology. See discussion at 66 Fed. Reg. at 868.

²⁷ 66 Fed. Reg. at 953. See commentary at 66 Fed. Reg. at 923.

²⁸ 66 Fed. Reg. at 924. For example, see the definition of "Radiology and certain other imaging services." 66 Fed. Reg. at 956.

²⁹ The concept of a "personally performed" service is included in our discussion of "referrals" at Section E.5 of this Article.

³⁰ 66 Fed. Reg. at 924.

³¹ The DHS listed in Section 1877(h)(6)(D) of the Act.

³² The DHS listed in Section 1877(h)(6)(E) of the Act.

³³ "Radiology services and radiation therapy and supplies means any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation, or nuclear medicine, and diagnostic mammography services, as covered under section 1861(s)(3) and (4) of the Act and Sections. 410.32(a), 410.34, and 410.35 of this chapter, including the professional component of these services, but excluding any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately." 63 Fed. Reg. at 1723.

statutory distinction between these two categories, the Phase I Final Regulations segregate "radiation therapy and supplies" from "radiology and certain other imaging services" and designate them as separate categories. In addition:

1.2.1. As discussed above in Section E.1.1 of this article, the "radiology and certain other imaging services" category as well as the other categories of DHS under Sections 1877(h)(6)(A)-(E) of the Act is defined for purposes of the Act by using lists of CPT and HCPCS codes, thus, any service not identified on the CPT/HCPCS List is not a "radiology or certain other imaging service" under the Phase I Final Regulations.³⁴ The commentary notes that the CPT/HCPCS List includes those services typically considered as radiology or ultrasound services, or as constituting an MRI or a computerized axial tomography ("CAT") scan.³⁵

1.2.2. Although ostensibly inconsistent with HCFA's purported departure from excluding services definitionally as DHS (see Section E.1.1 above), the commentary notes that "certain covered preventive screening procedures, such as screening mammography³⁶ that are subject to HCFA-imposed frequency limits that mitigate the potential for abuse"³⁷ are excluded from the CPT/HCPCS List and thus do not constitute "radiology and certain other imaging services."

1.2.3. The Phase I Final Regulations expressly exclude from the definition of "radiology and certain other imaging services" the following three types of services, even though they fit within the definition of "diagnostic tests or procedures using x-rays, ultrasound or other imaging services, CAT scans or MRI" that comprise this DHS category:

1.2.3.1. x-ray, fluoroscopy, and ultrasound services that are themselves invasive procedures that require the insertion of a needle, catheter, tube, or probe; as a result, cardiac catheterizations and endoscopies do not constitute "radiology services" for purposes of the Stark Law;³⁸

1.2.3.2. radiology procedures that are integral to the performance of, and performed during, a nonradiology medical procedure;³⁹ examples of these "integral" services include imaging guidance procedures and radiology procedures used to determine, during the performance of a surgery, whether the surgery is being conducted successfully;⁴⁰ and

³⁴ 66 Fed. Reg. at 956.

³⁵ Section 1861(s)(3) of the Act; 42 C.F.R. §§410.32, 410.34.

³⁶ "Diagnostic mammography services" were expressly included in the definition of "radiology services" under the Proposed Regulations. 63 Fed. Reg. at 1722.

³⁷ 66 Fed. Reg. at 927.

³⁸ 66 Fed. Reg. at 927. The commentary further explicitly indicates that all MRIs or CAT scans, however, are within the scope of DHS.

³⁹ This description is intended to clarify the characterization of this exception under the Proposed Regulations, which excluded "any invasive radiology procedure in which the imaging modality is used to guide a needle, probe or catheter accurately." 63 Fed. Reg. at 1722.

⁴⁰ 66 Fed. Reg. at 927.

1.2.3.3. "nuclear medicine"⁴¹ since, in HCFA's view, these services are not commonly considered to be radiology.⁴²

1.3. Home Health Services. Home health services⁴³ provided by a home health agency ("**HHA**") are not payable by the Medicare program unless a plan of care for such services has been certified (or recertified) by a physician.⁴⁴ Under the prior version of 42 C.F.R. §424.22(d), the required certification could not be provided by a physician who had either (i) a 5% or greater ownership interest in the HHA (*i.e.*, a significant ownership interest) or (ii) a financial or contractual relationship with the HHA with a value equal to or in excess of \$25,000 (*i.e.*, a significant financial relationship). The 5% ownership limit and the \$25,000 financial or contractual limitation has been removed and the regulation now permits a physician to certify or recertify the need for home health services to be provided by an HHA, or to establish or review a plan of treatment for an HHA, as long as the financial relationship between the physician and the HHA meets one of the relevant ownership or compensation exceptions under the Stark Law.⁴⁵

It is important to note here that physician services provided to a home health patient are not considered DHS unless the physician has performed a specific designated health service (*e.g.*, physical therapy). In such cases, the service would still be protected if personally performed by the referring physician since the provision of the service would not be a referral under the final rule.⁴⁶ In addition, some in-home services provided by a home care physician may be protected under the in-office ancillary services exception.⁴⁷

1.4. Inpatient and Outpatient Hospital Services. The Phase I Final Regulations expressly clarify in the definitions of both "inpatient hospital services" and "outpatient hospital services" that the services provided to a hospital's patients that are furnished either by the hospital itself or furnished "under arrangements" with others constitute DHS.⁴⁸ In the commentary, HCFA suggests that, in light of the description of "volume or value" standard under the Phase I Final Regulations,⁴⁹ "bona fide 'under arrangements' relationships can easily be structured to comply with the personal service arrangements exception, or, in some cases, the fair

⁴¹ " Nuclear medicine " was expressly included in the definition of "radiology services" under the Proposed Regulations. 63 Fed. Reg. at 1722.

⁴² 66 Fed. Reg. at 927.

⁴³ Home health services are those services described in Section 1861(m) of the Act and 42 C.F.R. part 409, subpart E.

⁴⁴ 42 C.F.R. §424.22(a)-(b)).

⁴⁵ 66 Fed. Reg. at 936-937.

⁴⁶ See discussion of the definition of a "referral" at Section E.5 below.

⁴⁷ See discussion of the in-office ancillary services exception at Section H.2 below. The commentary to the Phase I Final Regulations notes that the exception is available to services provided in a patient's home by a home care physician. 66 Fed. Reg. at 884.

⁴⁸ 66 Fed. Reg. at 954. Under the Proposed Regulations, "inpatient hospital services" were defined as "services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital." 42 C.F.R. §411.3511. For outpatient hospital services, although HCFA stated in the preamble of the Proposed Regulations that it would consider all covered services (either diagnostic or therapeutic) performed on hospital outpatients that are billed by the hospital to Medicare (including arranged for services) as outpatient hospital services, the definition in the Proposed Regulations did not specifically speak to services provided "under arrangements." 63 Fed. Reg. at 1682

⁴⁹ See discussion at Section E.6 of this Article.

market value exception."⁵⁰ This assurance notwithstanding, we recommend that any contractual arrangement between a hospital and a group practice pursuant to which the group furnishes hospital services "under arrangements" be carefully evaluated to ensure that it continues to satisfy an applicable exception. For example, any such arrangements in which the compensation to the group is based on a percentage of gross revenues or collections will not satisfy the "set in advance" requirement under the personal service arrangement exception⁵¹ or the FMV exception.

The Phase I Final Regulations also expressly clarify in the definitions of both "inpatient hospital services" and "outpatient hospital services" that professional services (*i.e.*, performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists and qualified psychologists) that Medicare pays independently of an inpatient or outpatient hospital service do not constitute DHS, nor do such services become DHS on account of being billed by a hospital under assignment or reassignment (*i.e.*, such services continue to be physician services).⁵² As discussed in detail in our discussion of "referrals" in Section E.5 below, when a physician initiates a DHS and then personally performs the service, that action would not constitute a "referral" for purposes of the Stark Law. The commentary points out, however, that, in the context of inpatient and outpatient hospital services, there nonetheless would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with any such personally performed service. By way of example, in the case of a surgeon who refers a patient for inpatient surgery and personally performs the operation, although there is no "referral" of the physician component of the surgery, there would be a referral of the technical component associated with the service.⁵³

1.5. Outpatient Prescription Drugs. The Stark Law provides that DHS include a category of "outpatient prescription drugs."⁵⁴ This term is not defined in the Stark Law, nor does Medicare cover a category of services designated as "outpatient prescription drugs." In the Proposed Regulations, this term was defined to include drugs (including biologicals) defined or listed under Section 1861 (s) and (t) of the Act, and in part 410, furnished under the Medicare Part B benefit that patients can obtain from a pharmacy with a prescription, even if patients can only receive the drug under medical supervision.⁵⁵ The Phase I Final Regulations expand the scope of this category to include "all prescription drugs covered by Medicare Part B" (*i.e.*, no outpatient prescription drugs are excluded from the DHS category of "outpatient prescription drugs," although there are a number of exceptions that relate to such drugs, as discussed below).⁵⁶

Although the scope of drugs comprising "outpatient prescription drugs" is more expansive than under the Proposed Regulations, as HCFA notes in the commentary, the relaxation of the exception for in-office ancillary services (with its more flexible direct supervision requirement) nonetheless reasonably permits physicians and physician groups to

⁵⁰ 66 Fed. Reg. at 942.

⁵¹ The personal service arrangement exception (and other exceptions covering compensation arrangements) are expected to be addressed in the Phase II Regulations.

⁵² 66 Fed. Reg. at 954.

⁵³ 66 Fed. Reg. at 941.

⁵⁴ Section 1877(h)(6)(J) of the Act.

⁵⁵ 63 Fed. Reg. at 1722.

⁵⁶ 66 Fed. Reg. at 955.

structure the delivery of outpatient prescription drugs in a manner that will enable the service to qualify for the exception.⁵⁷ In its discussion of physicians providing drugs in their own offices, HCFA clarified that there is no requirement for physicians to pass on to patients any Medicare discounts they receive in purchasing these drugs, unless otherwise required to do so by the Medicare program.⁵⁸

The definitional exclusion of EPO (*i.e.*, from the definition of "outpatient prescription drugs") under the Proposed Regulations is codified under the Phase I Final Regulations as an exception (under Section 411.355(g)) for EPO and certain other specific drugs that are required for the efficacy of dialysis when they are furnished by an ESRD facility with which the referring physician has a financial relationship. This exception, as well as the exceptions established under the Phase I Final Regulations for vaccinations, immunizations, and preventive screening tests subject to HCFA-imposed frequency limits, are discussed in detail in Section I.6 below.

2. Entity

Consistent with the Proposed Regulations, under the Phase I Final Regulations, an "entity" may be organized in one of several forms: a physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS.⁵⁹ The Phase I Final Regulations further expressly provide that an "entity" does not include the referring physician himself or herself, but does include his or her medical practice.⁶⁰ Therefore, when a physician refers to himself/herself, that act does not constitute a referral to an "entity" for purposes of the Stark Law. By contrast, when the physician orders a service which is furnished by another group practice member or from the practice's staff, that act constitutes a "referral" to the physician's practice.⁶¹

The definition of "entity" in the Phase I Final Regulations clarifies the discussion in the Proposed Regulations' commentary relating to the identity of the entity furnishing the DHS. In the preamble to the Proposed Regulations, HCFA indicated that it interpreted the "entity" to be the organization, corporation, etc. that actually furnishes, or arranges for the furnishing of, a service to a Medicare or Medicaid patient and bills for that service (or receives payment for the service from the billing entity as part of an "under arrangements" or similar agreement).⁶² The Phase I Final Regulations clarify that a person or entity furnishes DHS if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient's behalf, except that under certain circumstances if the person or entity reassigns its right to payment, the person or entity furnishing the DHS is the person or entity to which payment has been reassigned.⁶³

⁵⁷ The in-office ancillary services exception is discussed in detail at Section H.2 below.

⁵⁸ 66 Fed. Reg. at 938.

⁵⁹ 66 Fed. Reg. at 953.

⁶⁰ 66 Fed. Reg. at 953.

⁶¹ 66 Fed. Reg. at 943.

⁶² 63 Fed. Reg. at 1706.

⁶³ The reassignment scenarios specified in the definition of "entity" include reassignment to (i) an employer pursuant to 42 C.F.R. §424.80(b)(1), (ii) a facility pursuant to 42 C.F.R. §424.80(b)(2), or (iii) a health care delivery system, pursuant to 42 C.F.R. §424.80(b)(3) (other than a health care delivery system that is a health plan as defined

Further, in the Phase I Final Regulations, HCFA alters the position it had adopted in the preamble to the Proposed Regulations as to whether the owner of a DHS provider is considered to be equivalent to the entity providing DHS. Under the Proposed Regulations, a referring physician was constructively deemed to be the entity when the physician (or his/her immediate family member) has a significant ownership or controlling interest that enables the physician to control or influence the manner in which the entity conducts its business and with whom.⁶⁴ In lieu of this approach, the commentary to the Phase I Final Regulations clarifies that the determination as to whether a physician will be equated with an entity owned by a physician will be made by application of the rules related to indirect financial relationships and indirect referrals.⁶⁵

3. Fair Market Value

3.1. Elements of Fair Market Value. Consistent with the Proposed Regulations, the Phase I Final Regulations define "fair market value" ("FMV") as the "value in arm's-length transactions, consistent with the general market value."⁶⁶ Under this formulation, FMV requires that the compensation or price terms (i) be the product of bona fide bargaining (ii) between well-informed parties (iii) who are not otherwise in a position to generate business for the other party. Usually, FMV will be consistent with (i) the purchase price paid in connection with similarly situated sales transactions, or (ii) the compensation paid in connection with similarly situated service agreements.⁶⁷

With respect to the rental/lease arrangements, HCFA affirms the central principles articulated in the Proposed Regulations, albeit with significant clarifications. First, FMV is equivalent to the value of property being rented for general commercial purposes; this determination cannot take into account the lessee's intended use of the property. For example, it would be impermissible for a specialist (*e.g.*, a physical therapist) to pay a rental rate higher than that paid by other physicians in the medical office building for comparable space merely because there were a number of physician-tenants in the building who, by nature of their practice (*e.g.*,

in 42 C.F.R. §1000.952(l), and other than any managed care organization ("MCO"), provider-sponsored organization ("PSO"), or independent practice association ("IPA") with which a health plan contracts for services provided to plan enrollees). In the case of a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to the "reassignment to employer" or "reassignment to a facility" exceptions (under 42 C.F.R. §§424.80(b)(1) and(2)), the health plan, MCO, PSO, or IPA (as the case may be) is considered to be the entity furnishing DHS for any services provided by such supplier. See 66 Fed. Reg. at 943; commentary; 66 Fed. Reg. at 953 (definition at 42 C.F.R. §411.351).

⁶⁴ 63 Fed. Reg. at 1710.

⁶⁵ 66 Fed. Reg. at 943. See discussion in Section F below.

⁶⁶ "General market value" is defined as the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. In most cases, the fair market price is the price at which bona fide sales have been consummated for comparable assets (*i.e.*, assets of like type, quality, and quantity) in a particular market at the time of acquisition, or the compensation included in bona fide service agreements with comparable terms at the time of the agreement. 66 Fed. Reg. at 953.

⁶⁷ 66 Fed. Reg. at 953.

orthopedic specialties), might potentially be a source of patient referrals to the specialist.⁶⁸ Second, a rental payment cannot be adjusted to reflect the additional value that either party would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. In the commentary, HCFA interprets this requirement to apply solely to situations in which a physician is the lessor (*i.e.*, the limitation is inapplicable when a hospital leases space to a physician, even if the hospital is in a position to direct referrals to the physician). In fact, HCFA further posits that "a hospital should factor in the value of proximity when charging rent to lessee physicians."⁶⁹ Third, the definition adds a new qualification on the "taking into account intended use" prohibition, providing that "a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements." As a result, the rental rate can be established by reference to similar commercial property with comparable improvements or amenities of a similar value, irrespective of the reason for improving the property. Distilling all the rental-related guidance to one principle, the rental payments should be reasonably commensurate with those charged to similarly situated parties in arrangements in which referrals are not an issue.⁷⁰

3.2. Establishing Fair Market Value. HCFA adopts a relatively flexible position with respect to establishing that a transaction involving the payment of compensation for assets or services constitutes FMV. Specifically, in the commentary to the Phase I Final Regulations, HCFA announces its intent "to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another."⁷¹ Although not required, HCFA nonetheless suggests that it will give greater deference to independent valuations or comparables (discussed below). Below is a non-exclusive list of methodologies upon which parties may rely to demonstrate the FMV nature of an arrangement:

- i. obtaining an appraisal/valuation from a qualified independent expert;⁷²
- ii. establishing FMV by reference to comparable transactions, although there may be circumstances in which this approach cannot be applied because (a) there may not be a sufficient number of direct comparables (*e.g.*, rural areas), or (b) all the comparables in that particular market involve transactions between entities that are in a position to refer or generate other business;⁷³ or

⁶⁸ 66 Fed. Reg. at 945.

⁶⁹ 66 Fed. Reg. at 945.

⁷⁰ 66 Fed. Reg. at 945.

⁷¹ 66 Fed. Reg. at 944.

⁷² Although HCFA does not necessarily require that parties use an independent valuation consultant where other appropriate valuation methods are available, an independent valuation is preferred to an internally generated surveys, which "do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey." 66 Fed. Reg. at 944.

⁷³ Insofar as FMV represents that price that would be negotiated between well-informed parties *that are NOT in a position to refer or generate business for each other*, parties cannot reasonably rely on comparables in those situations in which all comparable transactions in the market involve parties who are in such a position (*e.g.*, if physician-owned equipment lessors have driven out all competitive third-party lessors of similar equipment); in such cases, the parties need to employ alternative valuation methodologies, such as cost plus reasonable rate of return (see

iii. alternative methodologies of finding a commercially reasonable representation of FMV (especially in circumstances where reliance on direct comparables is not possible), such as (a) comparing the arrangement at issue to similarly situated arrangements in a different market,⁷⁴ or (b) cost plus reasonable rate of return on investment on leases of comparable equipment from disinterested lessors.⁷⁵

In sum, no particular approach is mandated. In fact, under the circumstances, a method as simple as consulting a price list may suffice.⁷⁶ With respect to IRS guidelines for determining fair market (*i.e.*, which apply to tax exempt organizations), HCFA, while acknowledging that these constructively could be applied under certain circumstances, recognizes that the IRS' strictures might not be appropriate for for-profit entities.⁷⁷

As there is no single prescribed valuation methodology, there is similarly no "rule of thumb" as to the requisite amount of documentation that will be sufficient to substantiate FMV; rather, the amount of documentation is dependent upon the particular circumstances of the arrangement.⁷⁸ It is reasonable to posit that the extensiveness of the documentation will correlate, in most cases, to the anticipated degree of scrutiny to which the compensation component of the transaction likely will be subject. For example, HCFA takes the position that the valuation of a physician practice may include the value of DHS in the purchase price so long as the DHS provided by the selling physician is covered by an exception, such as the in-office ancillary services exception, and neither the transaction nor the price is contingent on future referrals.⁷⁹ In such a case, the level of scrutiny likely would be rather significant and, as a result, the parties to such a transaction would be well-advised to provide extremely thorough documentation to confirm the fairness of the price. In addition to documentation, HCFA recommends, under certain circumstances, that the parties consider obtaining good faith, written assurances as to FMV from the paying or receiving party, although such written assurances are by no means determinative.⁸⁰

4. Group Practice Arrangements

HCFA replaced the definition of "group practice" with a separate section in the regulations (411.352) setting forth nine standards for qualification as a group practice. HCFA's dual objectives were to minimize the regulatory intrusiveness of the definition and to provide clear guidance on what the requirements are for having a group practice. HCFA also views the

above). 66 Fed. Reg. at 944.

⁷⁴ In the commentary, HCFA points out that in regions with an insufficient number of direct comparables, it would be permissible to compare institutions or entities located in different, but characteristically similar, areas where property is zoned for similar use (*e.g.*, a university-affiliated hospital in one part of the country could be comparable to other university-affiliated hospitals that are located in similar types of communities).

⁷⁵ 66 Fed. Reg. at 944.

⁷⁶ 66 Fed. Reg. at 944.

⁷⁷ 66 Fed. Reg. at 944.

⁷⁸ 66 Fed. Reg. at 944.

⁷⁹ 66 Fed. Reg. at 877.

⁸⁰ 66 Fed. Reg. at 944.

new rules as providing substantial flexibility for structuring bona fide group practices. HCFA did not, however, intend to include as group practices loose confederations of physicians bound together primarily to profit from DHS referrals. Rather, HCFA will look at the extent to which "practices are fully integrated, medically and economically" and whether "their financial prospects are interdependent."⁸¹ Group practice arrangements are discussed at Section G below.

5. Referral

5.1. The Stark Law and related regulations define the term "referral" very broadly (i) any request by a physician for, ordering of, or certifying or recertifying the need for DHS; and (ii) any request or establishment of a plan of care by a physician that includes the provision of DHS, or the certifying or recertifying of the need for such a DHS.

5.2. There is also an express statutory exception that is maintained in the Phase I Final Regulations. Specifically, the term "referral" does not include the following requests:

- i. a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services;
- ii. a request by a radiologist for diagnostic radiology services; and
- iii. a request by a radiation oncologist for radiation therapy, if two conditions are met. First, the request must result from a consultation initiated by another physician (whether to a particular physician or an affiliated entity). Second, the tests or services must be furnished by or under the supervision of the pathologist, radiologist or radiation oncologist.

5.3. HCFA has revised the definition of "referral" to exclude any designated health service that is personally performed or provided by the referring physician. Personally performed services, at least in this context, do not include services performed by any other person (e.g., employee, independent contractor or group practice member). In other words, true self-referrals would not be prohibited or require any exception.⁸²

5.3.1. HCFA considered and rejected comments suggesting that there is no "referral" for Stark Law purposes where the services are performed by the referring physician's employees generally or limited to "incident to" services. The rationale articulated by HCFA included that such a narrowing of the definition of referral may lead to circumvention of the location requirement for in-office ancillary services and that the expansion of the in-office ancillary services exception would cover services performed by a physician's employees "in most cases." HCFA did note, however, that it is specifically soliciting comments on whether, and under what circumstances, services performed by a physician's employees could be treated as personally performed by the physician.⁸³

⁸¹ 66 Fed. Reg. at 895.

⁸² 66 Fed. Reg. at 956.

⁸³ 66 Fed. Reg. at 871-72.

5.3.2. With respect to referrals by a nurse practitioner or physician assistant employed by a physician, HCFA indicated in the preamble that it will use a facts and circumstances approach to determine whether the referral should be imputed to the employer. The question will be whether or not the physician controls or influences the nonphysician's referral. If so, the referral would be treated as an indirect referral made by the controlling physician.⁸⁴

5.4. HCFA added a definition of "consultation" to respond to comments that the line between consulting and treatment was often not ascertainable. Under the Phase I Final Regulations, "consultation" means a professional service furnished to a patient by a physician if four conditions are satisfied: (i) another physician requested the opinion or advice regarding evaluation or management of a specific medical problem; (ii) that request and the need for the consultation are documented in the medical record; (iii) after the consultation, the physician prepares a written report of his or her findings and provides it to the physician who requested the consultation; and (iv) with respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation if the radiation oncologist communicates with the referring physician regularly as to the patient's course of treatment and progress.⁸⁵

5.4.1. This definition was included for the limited purpose of applying the exception for certain orders of DHS by a pathologist, diagnostic radiologist or radiation oncologist (in the definition of "referral"). In that regard, the last element recognizes that radiation therapy, in particular, may extend over a significant length of time.⁸⁶

5.4.2. HCFA declined to permit supervision by anyone other than the consulting physician, stating that such a provision would be contrary to the "plain language of Section 1877(h)(5)(C) of the Act." HCFA did note, however, that it is broadly interpreting "supervision" in this context to be consistent with the general supervision requirements for the Medicare program for such services.⁸⁷

5.5. The new regulations also are adapting Stark to the e-commerce age by specifying that a referral can be in any form, including written, oral or electronic.⁸⁸ Yet HCFA also notes in the preamble that it is "establishing an exception for indirect and oral referrals."⁸⁹ This comment likely refers to the new exception in Section 411.353(e) for payments made to an entity that submits a claim for DHS without actual knowledge of, and without acting in reckless disregard or deliberate ignorance of the identify of the referring physician and the claim otherwise complies with applicable Federal law, rules and regulations. That would be consistent with HCFA's further explanation in the preamble that this exception for indirect or oral referrals means that, in the absence of a written order or other documentation of the referral, the issue

⁸⁴ 66 Fed. Reg. at 872, 880.

⁸⁵ 66 Fed. Reg. at 953.

⁸⁶ 66 Fed. Reg. at 873, 956.

⁸⁷ 66 Fed. Reg. at 875.

⁸⁸ 66 Fed. Reg. at 956.

⁸⁹ 66 Fed. Reg. at 872.

should be whether the provider knows or has reason to suspect the identity of the referring physician. This exception, even though effectively limited to indirect and oral referrals, should protect providers from inadvertent violations of the Stark Law. It will not, however, permit providers to bury their heads in the sand if they have reason to know the identity of the referring physician (and that he or she may have a financial relationship with the entity providing the DHS).

6. Volume or Value/Set In Advance/Other Business Generated

6.1. General. The terms "*volume or value*," "*set in advance*," and "*other business generated*" are integral components of various exceptions and definitions, under the Stark Law and Phase I Final Regulations, that circumscribe the means by which a physician permissibly may be compensated for purposes of fitting within the particular exception or definition. A "volume or value" standard (*i.e.*, "takes into account the volume or value of any referrals by the referring physician," as described in greater detail in Section 6.2 below) is included within the following exceptions: (i) employment relationships, (ii) personal service arrangements, (iii) rental of office space, (iv) rental of equipment, (v) physician recruitment, (vi) isolated transactions, (vii) group practice arrangements with a hospital,⁹⁰ (viii) fair market value, (ix) non-monetary compensation under \$300, (x) hospital medical staff benefits, academic medical centers, and (xi) indirect compensation arrangements, as well as in the definitions of "group practice" and what constitutes a "indirect compensation arrangement." In connection with certain exceptions and definitions, the scope of the volume or value standard is expanded to include the additional restriction that the payment may not take into account "other business generated between the parties."⁹¹ In addition, to qualify for certain exceptions,⁹² compensation must be "set in advance."

6.2. "Volume or Value". HCFA's interpretation of the "takes into account the volume or value of referrals standard" under the Phase I Final Regulations (which, according to the commentary, will be applied consistently in all exceptions and definitions using that term)⁹³ may enable entities to enter into certain contractual relationships with physicians that the Proposed Regulations would have prohibited. In particular, the Phase I Final Regulations differ from the Proposed Regulations in two significant respects. First, provided that certain conditions

⁹⁰ The compensation exceptions identified in clauses (i) through (vii) (set forth in Section 1877(e) of the Act) are not addressed in the Phase I Final Regulations, but are expected to be covered in the Phase II Regulations.

⁹¹ The volume or value standard includes the phrase, "other business generated," in each of the exceptions discussed above, with the exception of the employment, physician recruitment and isolated transaction exceptions. In addition, the volume or value standard in the definition of an indirect compensation arrangement also applies to "other business generated."

⁹² Compensation must be set in advance for purposes of exceptions for personal service arrangements, rental of office space/equipment, group practice arrangements with a hospital, fair market value, and academic medical centers.

⁹³ As discussed below in Section F.6 (regarding indirect compensation arrangements), the scope of the phrase, "*takes into account the volume or value ...*" (*i.e.*, the standard for the indirect compensation arrangement exception and **[each]** of the other proposed exceptions under the Phase I Final Regulations) appears to be narrower than the formulation of the standard in the definition of an indirect compensation arrangement, "*varies with, or otherwise reflects, the volume or value ...*". Thus, compensation potentially can be determined in a manner that "reflects" the referring physician's referrals, but nonetheless does not "take into account" those referrals, based on HCFA's interpretation of per unit-of-service arrangements (discussed above).

(discussed below) are met, a contractual arrangement pursuant to which a physician's compensation is established on a fixed time-based or per unit of service-based amount (*e.g.*, an equipment rental arrangement with payments on a "per-click" basis) will not violate the volume or value standard, even if the compensation received by the physician includes amounts that relate to his or her referrals. Secondly, the conditioning of a physician's compensation on his or her referring patients to a particular provider or supplier will not be considered to take into account value or volume of referrals, so long as the arrangement satisfies certain requirements (discussed below).

Under the Proposed Regulations, compensation could be based on units of service (such as "per-click" equipment rentals) if, but only if, the units of service did not include services provided to patients who were referred by the physician receiving the payment.⁹⁴ The Phase I Final Regulations expressly eliminate this restriction, stating that compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account "the volume or value of referrals" so long as the compensation (i) is FMV for services or items actually provided, and (ii) does not vary during the agreement's term in any manner that takes into account referrals of DHS.⁹⁵ Thus, the critical element is that the compensation methodology must either remain constant or, if it changes during the term, there is no nexus between that change and the referring physician's DHS. This is significantly different from a standard in which the compensation itself cannot, in any way, reflect the referring physician's referrals (*i.e.*, any DHS that result from the physician's referrals would have to be excluded for purposes of calculating compensation). By way of example, if a physician were to lease equipment to a hospital (*i.e.*, with which the hospital furnishes DHS) on a "per-click" basis, it would be permissible for the hospital to make rental payments to the physician-lessor, even for services performed on patients that he or she referred, provided that the "per-click" rental payment is consistent with FMV, remains fixed over the lease term, and the arrangement otherwise qualifies for the rental exception.⁹⁶ Although not stated directly in the rules or the commentary, when structuring per unit-of-service arrangements in which the physician-lessor is a potential referral source, it is advisable (i) to ensure that the lessee is not paying the physician-lessor a higher unit rate than it pays for the same or similar equipment to a person or entity who is not in a position to refer, and (ii) absent compelling reasons, to avoid modifying the unit rate during the course of the arrangement (or, if for some reason it is necessary to modify the amount, to compile adequate documentation to credibly demonstrate that there is no connection whatsoever between the rental rate amendment and the physician-lessor's referrals to the lessee).

Under the Proposed Regulations, HCFA adopted the view that the volume or value standard affects not only arrangements where "a physician's payments from an entity fluctuate in a manner that reflects referrals," but also certain situations where "a physician's payments from an entity are stable, but predicated, either expressly or otherwise, on the physician making referrals to a particular provider."⁹⁷ In other words, if the amount a physician can receive is fixed but whether he or she receives the fixed amount is dependant on whether he or she makes

⁹⁴ See commentary at 63 Fed. Reg. at 1699 and example at 63 Fed. Reg. at 1714.

⁹⁵ 66 Fed. Reg. at 876; commentary; 66 Fed. Reg. at 959 (42 C.F.R. §411.354(d)(2)).

⁹⁶ Compare to example under the Proposed Regulations at 63 Fed. Reg. at 1714 (in which HCFA stated that "the rental payments cannot reflect 'per-click' payments for patients who are referred for the service by the lessor physician").

⁹⁷ 63 Fed. Reg. at 1699, 1700.

referrals to a particular provider, the arrangement may violate the volume or value standard. HCFA, however, has adopted a contrary approach in the Phase I Final Regulations, taking the position that an otherwise acceptable compensation arrangement for physician services will not implicate the volume or value standard solely because, as a condition of the payment under the arrangement, the physician must refer to a particular provider or supplier. In order to avoid triggering the volume or value standard an such arrangement conditioned on referrals should meet the following conditions: (i) the terms governing the referral obligations must be memorialized in a signed agreement, (ii) the payment thereunder, in addition to being fixed in advance for the term of the arrangement, must be FMV for the services performed (*i.e.*, the payment must not take into account the volume or value of the anticipated or required referrals from the physician), (iii) the arrangement otherwise must comply with the requirements of an applicable Stark Law exception, and (iv) the arrangement must expressly provide exceptions to enable the physician to refer to a non-designated provider or supplier (a) when the patient expresses a different choice, (b) when the patient's insurer determines the provider, or (c) when the referral is not in the best medical interest of the patient in the physician's judgment.⁹⁸ As an example, an employer or a managed care contract permissibly may mandate that a physician refer to certain providers (*e.g.*, within that employer's or managed care plan's network) and, so long as the arrangement complies with the standards described above, the arrangement will not be violative of the Stark Law. Further, in the commentary, HCFA clarifies that it distinguishes a non-compete covenant from an affirmative obligation imposed upon a physician who sells his or her medical practice to refer business to the purchaser. Whereas, in HCFA's view, a non-compete restriction does not implicate the volume or value standard, the inclusion in the purchase agreement of a requirement that the physician-seller refer business to the purchaser likely would subject the transaction to heightened scrutiny under the Anti-kickback Statute.⁹⁹

6.3. "Other Business Between The Parties. The scope of the limitation that "compensation cannot be determined in a manner that takes into account the volume or value of any referrals" is expanded to include "other business generated between the parties" in the majority of exceptions applying the volume or value standard (*i.e.*, exceptions for personal service arrangements, rental of office space/equipment, group practice arrangements with a hospital, fair market value, non-monetary compensation under \$300, hospital medical staff benefits, academic medical centers, and indirect compensation arrangements). The Phase I Final Regulations further explicate the meaning of the phrase, as discussed in the commentary to the Proposed Regulations (*i.e.*, that "the payment in an arrangement had to be fair market value for the services expressly covered by the arrangement and could not include any payment for services not covered by the arrangement").¹⁰⁰ First, HCFA interprets the phrase, "business generated between the parties," to mean business generated for the entity by the referring physician.¹⁰¹ Second, the Phase I Final Regulations specifically provide that compensation (including time-based or per unit of service-based compensation) will be deemed to not take into account "other business generated between the parties" so long as two standards are met: (i) the compensation is FMV, and (ii) the compensation does not vary during the term of the agreement

⁹⁸ See 66 Fed. Reg. at 877; commentary; 66 Fed. Reg. at 959 (42 C.F.R. §411.354(d)(4)).

⁹⁹ 66 Fed. Reg. at 878-79.

¹⁰⁰ 63 Fed. Reg. at 1699.

¹⁰¹ 66 Fed. Reg. at 876. In fact, the Phase I Final Regulations, in connection with certain exceptions, refers to "other business generated by the referring physician" (*e.g.*, the fair market value and non-monetary compensation under \$300 exceptions).

in any manner that takes into account referrals or other business generated by the referring physician; for purposes of this standard, "other business generated" expressly includes "private pay health care business" that the referring physician generates.¹⁰² HCFA views this standard to mean that a fixed, FMV payment cannot be established based upon, nor may that fixed amount vary during the term of the arrangement, by reference to the referring physician's referrals or ability to generate federal or private business for the DHS entity.¹⁰³ Thus, just as it is permissible for a physician to lease an MRI machine to a hospital on a per-click basis (provided that the rate is consistent with FMV) and for the per-click payments to include services furnished by the hospital (*i.e.*, resulting in uses of the machine and thus payments to the physician) to Medicare patients referred by the physician-lessor (see discussion in Section 6.2 above), the per-click payments may also include services furnished by the hospital to private pay patients referred by the physician-lessor. Conversely, if the "per-click" rate either was inflated based on anticipated referrals of private pay patients by the physician-lessor, or the rate changed during the term of the arrangement based upon the physician-lessor's referrals of private pay patients, then this standard would be implicated, resulting in the arrangement violating the Stark Law insofar as the compensation to the physician would be deemed to take into account other business generated between the parties.

6.4. "Set In Advance". Compensation must be "set in advance" for an arrangement to fit within the exceptions for personal service arrangements, rental of office space/equipment, group practice arrangements with a hospital, fair market value, and academic medical centers. Pursuant to the definition in the Phase I Final Regulations, compensation is deemed to be "set in advance" if the parties' agreement prescribes with reasonable specificity the terms governing the exchange of compensation between the parties, either as (i) the aggregate compensation under the arrangement or (ii) a time-based or per unit of service-based amount (*i.e.*, it is not necessary to specify the aggregate compensation).¹⁰⁴ Thus, the compensation terms must be fixed and objectively verifiable, and may not fluctuate during the term of the agreement. In addition, to qualify as "set in advance," the amount of the payment must be consistent with FMV for the services (or items) that the referring physician actually provides, which amount cannot take into account the volume or value of referrals or other business generated by the referring physician (see discussion above). Further, the definition of the term expressly excludes percentage arrangements "in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser."¹⁰⁵ As a result, most percentage compensation arrangements will not be deemed to be "set in advance" because the percentage compensation is measured by reference to a single standard that does not remain constant throughout the term. In the commentary, HCFA indicates that payments based upon a percentage of either (i) gross revenues, (ii) collections, or (iii) expenses will *not* be considered to be fixed in advance. If, however, a physician were to be paid a percentage of a single fee schedule (*i.e.*, the hospital does not accept different amounts from different payors), the arrangement would qualify as "set in advance."¹⁰⁶

¹⁰² 66 Fed. Reg. at 959 (42 C.F.R. §411.354(d)(3)).

¹⁰³ 66 Fed. Reg. at 877.

¹⁰⁴ See 66 Fed. Reg. at 877; commentary; 66 Fed. Reg. at 959 (42 C.F.R. §411.354(d)(1)).

¹⁰⁵ 66 Fed. Reg. at 959 (42 C.F.R. §411.354(d)(1)).

¹⁰⁶ 66 Fed. Reg. at 877-78.

F. FINANCIAL RELATIONSHIPS/COMPENSATION /OWNERSHIP INTERESTS

1. Financial Relationship

Consistent with the statutory formulation, a "financial relationship" may arise from either (i) a direct or indirect ownership or investment interest in a DHS entity, or (ii) a direct or indirect compensation arrangement with a DHS entity.¹⁰⁷ The Phase I Final Regulations clarify that a "direct financial relationship" exists if remuneration passes between the referring physician (or his/her immediate family member) and the DHS entity without any intervening parties (*i.e.*, the arrangement exists, and thus compensation passes, directly between the referring physician and the DHS entity without any other person or entity interposed between the parties).¹⁰⁸ In a number of significant respects (discussed below), the Phase I Final Regulations alter the scope of what constitutes an "indirect financial relationship," which comprise (i) indirect ownership or investment interests and (ii) indirect compensation arrangements.

Under the Proposed Regulations, HCFA interpreted the scope of indirect financial relationships expansively, with the result that even attenuated connections between a referring physician and a DHS entity potentially could form the basis for a financial relationship. Specifically, under the former interpretation, an indirect ownership/investment interest could arise from any ownership or investment interest in the DHS entity, irrespective of how indirect or remote, and an indirect compensation relationship could be established by tracing compensation paid by an entity furnishing DHS itself or through other entities, without regard to whether the physician's compensation (*i.e.*, from the entity with which he or she had a direct compensation arrangement) bore any connection to the physician's referrals to the DHS entity.¹⁰⁹ The principal changes adopted by the Phase I Final Regulations with respect to financial relationships include: (i) clarifying the distinction between a direct and indirect financial relationships; (ii) adding a "knowledge" element to the definition of indirect financial relationships; (iii) creating a new exception for indirect compensation arrangements; and (iv) clarifying that payment obligations that are secured, including those secured by a revenue stream, constitute ownership or investment interests (rather than compensation arrangements).¹¹⁰ Also, as discussed elsewhere in this article, the revision of the definition of "referral" to exclude services (including DHS) personally performed by the referring physician, as well as the creation of a new exception permitting payment to entities submitting claims for DHS that did not know of and did not have reason to suspect the identity of the physician who made the referral to the DHS entity, each contributes to the relaxation of the financial relationships standards under the Stark Law. As discussed in greater detail below, the Phase I Final Regulations essentially prohibit referrals for DHS from a referring physician to an entity with which he or she has an indirect financial relationship solely if:

- (i) either (a) there exists an unbroken chain of ownership or investment interest between the referring physician (or immediate family member) and the DHS

¹⁰⁷ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(a)(1)).

¹⁰⁸ See 66 Fed. Reg. at 864; commentary; 66 Fed. Reg. at 958 (42 C.F.R. §411.354(d)(2)).

¹⁰⁹ See 63 Fed. Reg. at 1686.

¹¹⁰ 66 Fed. Reg. at 864.

entity (*i.e.*, an indirect ownership/investment interest), or (b) the referring physician receives aggregate compensation that varies with, or otherwise reflects, referrals or other business generated by the referring physician for the DHS entity (*i.e.*, an indirect compensation arrangement);

(ii) the DHS entity either (a) has "actual knowledge" (as HCFA interprets that term) that the referring physician (or immediate family member) has an indirect financial relationship, or (b) acts in reckless disregard or deliberate ignorance of such an indirect financial relationship's existence; and

(iii) the arrangement does not qualify for the indirect compensation arrangement exception.

2. Ownership or Investment Interest

The Phase I Final Regulations track the statutory definition of an "ownership or investment interest," which "may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS."¹¹¹ Consistent with the Proposed Regulations' formulation, an ownership/investment interest may comprise stock, partnership shares, limited liability company memberships, etc. HCFA also expressly clarifies that financial interests (such as loans, bonds, etc.) secured with an entity's property or revenue (or a portion thereof) fall within the definition of an ownership or investment interest.¹¹² Conversely, payment obligations that are unsecured (such as an unsecured loan that is subordinated to a credit facility) constitute compensation arrangements.¹¹³ Other interests expressly excluded from the definition of an ownership/investment interest include (i) interests in a retirement plan,¹¹⁴ (ii) stock options and convertible securities until such time as the stock options are exercised or the convertible securities are converted to equity,¹¹⁵ and (iii) an "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital.¹¹⁶ Further, the interest, dividends, profit distributions, etc. derived from an excepted ownership/investment interest will not have to separately meet an exception for a compensation arrangement (*i.e.*, for purposes of the Stark Law, the payments flowing from the ownership/investment interest are constructively deemed to be part of such interest).¹¹⁷ The final significant clarification offered by the Phase I Final Regulations with respect to ownership/investment interests is that an ownership /investment interest in a subsidiary is neither an ownership or investment interest in the parent company, nor in any "brother-sister"

¹¹¹ 42 U.S.C. §1395nn(a)(2) (Stark Law); 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b); Phase I Final Regulations).

¹¹² 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(1)).

¹¹³ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(3)(iii)).

¹¹⁴ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(3)(i)). This position alters the approach discussed in the preamble to the Proposed Regulations. In the Phase I Final Regulations, HCFA indicated that contributions to a retirement account (even those from the employer) are to be considered part of the employee's overall compensation. 66 Fed. Reg. at 870; commentary.

¹¹⁵ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(3)(i)). HCFA interprets stock options to be compensation at the time they are granted. 66 Fed. Reg. at 870; commentary.

¹¹⁶ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(3)(iv)). The definition of "compensation arrangement" expressly states that such an "under arrangements" agreement constitutes a compensation arrangement. 42 C.F.R. §411.354(c)

¹¹⁷ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(4)).

companies (*i.e.*, other subsidiaries of the parent), unless the subsidiary itself has an ownership/investment interest in the parent or other brother-sister entities.¹¹⁸ Therefore, if Company A owns Company B and Company C, and a physician has an ownership interest in Company B, he or she will not be considered to own either Company A (the parent) or Company C (the brother-sister company), unless Company B holds an ownership or investment interest in either of them.

3. Compensation Arrangement

Consistent with the definition in Section 1877 of the Act, a "compensation arrangement" can be any arrangement involving remuneration, direct or indirect, between a physician (or immediate family) and an entity. The definition of the term in the Phase I Final Regulations affirms that a compensation arrangement does not include either (i) an arrangement involving only certain types of remuneration (*e.g.*, forgiveness of amounts for inaccurate tests, procedures, etc.; furnishing of items, devices, etc. for the collection or transport to the DHS entity or for the communication of results from the DHS entity; or certain payments by an insurer or self-insured plan to a physician to satisfy a claim submitted on a fee-for-service basis, which are specifically described in clauses (i)-(iii) of the definition of "remuneration"), or (ii) payments made by a consultant to a referring physician for consultations via interactive telecommunications systems (*i.e.*, telemedicine) under 42 C.F.R. § 414.65(e).¹¹⁹

4. Knowledge/Duty of Reasonable Inquiry

In a significant deviation from the Proposed Regulations, the establishment of an "indirect ownership and investment interest" and an "indirect compensation arrangement" under the Phase I Final Regulations each requires, among other things, that the DHS entity have knowledge of the indirect financial relationship with the referring physician (or an immediate family member), or otherwise act in reckless disregard or deliberate ignorance thereof. In the commentary, HCFA notes that this "knowledge" element generally imposes a duty of reasonable inquiry, which does not impose an affirmative obligation to inquire as to indirect financial relationships, but does require that a party, if aware of certain facts that would lead a reasonable person to suspect the existence of an indirect financial relationship, to take reasonable steps to determine whether such a financial relationship exists and, if so, whether an exception applies that will permit the DHS entity to bill for services referred by the referring physician. HCFA does not enumerate what specific actions (*i.e.*, that potentially may be taken by a provider) will constitute "reasonable steps" for purposes of the knowledge inquiry; rather, the actions should be guided by the particular circumstances of the transaction. One potential approach suggested by HCFA in the commentary, however, is for the DHS entity to request, in good faith, from either the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation, a good faith, written assurance that the physician's (or immediate family member's) aggregate compensation is FMV for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity. While constructive to demonstrate that the parties took reasonable steps, these written assurances will not be

¹¹⁸ 66 Fed. Reg. at 867; commentary; 66 Fed. Reg. at 958 (42 C.F.R. §411.354(b)(2)).

¹¹⁹ 66 Fed. Reg. at 958 (42 C.F.R. §411.354(c)(1)).

considered determinative.¹²⁰ Thus, if a DHS entity has reason to suspect that the information to which the physician or group attested is not accurate, the entity is not relieved of the obligation to take other reasonable steps to ascertain whether an indirect financial relationship, in fact, exists and, if so, whether the arrangement nonetheless is covered by an applicable exception. In developing such a form of certification for purposes of the knowledge inquiry, hospitals and other providers need to explain, with sufficient clarity, the meaning of the "volume or value" standard so as to be reasonably intelligible to the providers asked to sign these documents.

5. Indirect Ownership Or Investment Interest

To establish an "indirect ownership or investment interest," two elements must be present: (i) there must be an unbroken chain of persons or entities (*i.e.*, through one or more intermediate entities) having ownership or investment interests between them, and (ii) the DHS entity must either have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest, albeit indirect (*i.e.*, there are one or more parties interposed between them in the ownership chain), in the DHS entity. For purposes of this provision, the "knowledge" element does not require knowledge as to the specific composition of the referring physician's ownership/investment; rather, the DHS entity need only know or have reason to suspect that the referring physician (or immediate family member) has some ownership investment interest in the DHS entity (or in an entity that holds such an interest in the DHS entity). By way of example, if (i) a hospital has a contractual obligation to make interest payments to a physician, which payment obligation is secured by the hospital's accounts receivable (*i.e.*, and thus the physician is deemed to have an ownership interest in the hospital), and (ii) the hospital has a 50% ownership interest in a home health agency, then, the issue of whether the physician will be deemed to have an indirect ownership interest in the home health agency turns on whether that entity had knowledge of the physician's interest in its 50% owner, the hospital.

6. Indirect Compensation Arrangement

The most sweeping changes introduced by the Phase I Final Regulations with respect to financial relationships relate to indirect compensation arrangements, the establishment of which require three elements: (i) there must exist between the referring physician (or immediate family member) and the DHS entity an unbroken chain of persons or entities with financial relationships between them (*i.e.*, each link in the chain must have either an ownership/investment interest in, or compensation arrangement with, the preceding link);¹²¹ (ii) the aggregate compensation

¹²⁰ 66 Fed. Reg. at 865.

¹²¹ The unbroken chain that creates an indirect compensation arrangement may comprise any combination of excepted or *unexcepted* financial relationships, irrespective of whether they are ownership/investment interests or compensation arrangements. An excepted financial relationship (*i.e.*, one that qualifies for an applicable exception under the Stark Law) may nonetheless constitute a link in a chain that establishes an indirect compensation arrangement between a referring physician and a DHS entity. In the commentary, HCFA gives the example of a referring physician, who owns an interest in a hospital that meets the "whole hospital" ownership exception under section 1877(d)(3) of the Act, and the hospital contracts for services with a clinical laboratory to which the physician refers, there would exist an unbroken chain of persons or entities having financial relationships between the referring physician and the DHS entity (referring physician → hospital → clinical laboratory), even though the financial relationship between the referring physician and the hospital is covered by an exception. 66 Fed. Reg. at 866.

received by the referring physician (or immediate family member) from the person or entity in the chain with which the physician has a direct financial relationship (the "**directly compensating entity**") *varies with, or otherwise reflects*, the volume or value of referrals or other business generated by the referring physician for the DHS entity; and (iii) the DHS entity must have actual knowledge that the aggregate compensation received by the referring physician (or immediate family member) from the entity with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the DHS entity, or otherwise must act in reckless disregard or deliberate ignorance of the existence of such relationship.

With respect to those cases in which the financial relationship between the physician (or immediate family member) and the directly compensating entity is an ownership or investment interest (*i.e.*, in which case, that entity is also an "**owned entity**"), the determination as to whether his or her aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated for the DHS entity is measured by the terms of the compensation arrangement closest in the chain to the referring physician (or immediate family member). In other words, the "varies with, or otherwise reflects" inquiry examines the first compensation arrangement in the chain with a party that is not an owned entity (*i.e.*, an "**unowned entity**"). In the event that the owned entity itself has a compensation arrangement with an unowned entity, the inquiry is whether the aggregate compensation paid to that owned entity varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the DHS entity; in the event, however, that the owned entity has an ownership/investment interest in another entity (*i.e.*, the second-tier owned entity), which then has a compensation arrangement with an unowned entity, that "volume or value" inquiry will focus on whether compensation to the second-tier owned entity varies or otherwise reflects the physician's referrals or other business to the DHS entity (Note that although the compensation analysis focuses on the terms of the closest owned entity's agreement with an unowned entity, the question is whether those compensation terms reflect the physician's referrals to the DHS entity, which may be the unowned entity or another entity with which the unowned entity has a financial relationship, as in HCFA's example (discussed below)). The definition gives the example of a referring physician, who has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS; in such case, HCFA states that it would look to the aggregate compensation between company B and company C to determine if it varied, or otherwise reflected, the value or volume of the referring physician's referrals or other business that he generated for company D.¹²²

For the purpose of determining whether an indirect compensation arrangement exists, the Phase I Final Regulations include a formulation of the "volume or value" standard that differs from, and is broader than, the standard applied in connection with other exceptions (including the exception for indirect compensation arrangements). Thus, an arrangement potentially might implicate the "volume or value" standard used for the definition of an indirect compensation arrangement (*i.e.*, "varies, or otherwise reflects, the value or volume ..."), but the compensation under that same arrangement nonetheless might not be considered to "take into account the value or volume ..." and thus not implicate the standard for purposes of exceptions, such as the indirect

¹²² See 66 Fed. Reg. at 866; commentary; 66 Fed. Reg. at 959 (42 C.F.R. §411.354(b)(2)).

compensation arrangement exception. As noted above, the definition of indirect compensation arrangement examines whether aggregate compensation between the non-owned entity and the owned entity (or the first entity in the ownership chain with a compensation arrangement therewith) *varies with, or otherwise reflects*, the value or volume of referrals or other business generated by the referring physician for the DHS entity. The commentary notes that, for purposes of this element, any "per service" or "per use" payment arrangement between the physician and the directly compensating entity that is based, in whole or in part, on referrals or other business generated for the DHS entity would satisfy the "volume or value" element in the definition. By contrast, HCFA does not interpret "per service" or "per use" payment arrangements to "take into account the volume or value" of referrals or business, provided that the payment is FMV and does not vary during the term of the arrangement in a manner that takes into account referrals. (See discussion in Section E.6.2 above.)

In order to illustrate the type of arrangement that constitutes an indirect compensation arrangement (and, in the process, the breadth of the "otherwise reflects" formulation of the "volume or value" standard), the commentary offers the example of a physician who owns a PT company and then refers patients for treatment (including PT) to a SNF that contracts with his PT company (with payments thereunder on a per service basis). HCFA explains that, in this situation, there would be an indirect compensation relationship between the SNF, which is the DHS entity, and the referring physician. Since the SNF acquires PT services from the PT company owned by the referring physician, a compensation arrangement exists between the SNF and the PT company, and an ownership interest exists between the referring physician and the PT company. As a result, the first prong, an unbroken chain of financial relationships, is met. With respect to the second prong, since the financial relationship between the referring physician and the directly compensating entity (in this case, the PT company) is an investment interest, the inquiry focuses on the compensation paid by the SNF to the owned entity (in this case, the PT company) in order to determine if the second element is satisfied. The commentary then notes that "since the PT company is compensated on a per service basis that reflects referrals by the referring physician to the SNF, the second element is met."¹²³ Although not expressly stated in the commentary, the rationale is that, because payments under the contract between the PT company and the SNF are on a per service basis, the fact that the PT company will generate more business on account of the referring physician's referrals to the SNF (which contracts with the PT company for services) means that the compensation "otherwise reflects" the volume or value of the referring physician's referrals to the SNF, which is the DHS entity. Thus, assuming that the SNF had requisite knowledge of the financial relationships, an indirect compensation arrangement would be established; in such case, the referring physician would be permitted to make referrals to the SNF only if the arrangement qualified for the exception for indirect compensation arrangements (discussed below).

7. Exception for Indirect Compensation Arrangements

As referenced above, a particular arrangement might satisfy all the elements required to establish an indirect compensation arrangement, but nonetheless qualify for the new exception under the Phase I Final Regulations covering indirect compensation arrangements. In fact, without the exception, certain arrangements that would be protected if entered into directly

¹²³ 66 Fed. Reg. at 868.

between the referring physician and the DHS entity (*e.g.*, a physician leasing an MRI machine to a hospital with fixed, FMV per-click payments, including for imaging services rendered to patients referred by the physician) could not be accomplished indirectly (*e.g.*, a physician referring to a hospital which contracted for MRI services with a company owned by physician, with fixed, FMV per-click payments). In the former case, there is a direct compensation arrangement to which the "does not take into account" standard applies; as discussed in Section E.6.2 of this article, per-click payments do not implicate the "takes into account volume or value" standard where the payments are FMV and fixed throughout the term. Conversely, in the latter case, assuming requisite knowledge by the hospital of the financial relationships, the referring physician will be deemed to have an indirect compensation arrangement with the hospital; since the MRI company will generate more revenue each time the referring physician refers a patient to the hospital requiring MRI imaging services, the contract between the hospital and the MRI company will "reflect" the volume or value of the referring physician's referrals. Accordingly, the exception for indirect compensation arrangements is intended, in practice, to equalize direct and indirect arrangements.

In order to fit within this exception, the arrangement must comply with three requirements:¹²⁴ (i) the compensation received by the referring physician (or immediate family member) from the directly compensating entity must be FMV for the items or services provided under the arrangement and must not take into account the value or volume of referrals or other business generated by the referring physician for the DHS entity;¹²⁵ (ii) the compensation arrangement between the referring physician (or immediate family member) and the directly compensating entity must be set out in writing, signed by the parties, and specify the services covered by the arrangement (except a bona fide employment relationship need not be set out in a written contract, but nonetheless must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and (iii) the compensation arrangement must not violate the Anti-kickback Statute or any laws or regulations governing billing or claims submission. Further, consistent with the definition of an indirect compensation arrangement, the analysis under which examines the compensation arrangement in the chain closest to the referring physician where the financial relationship between the physician and the directly compensating entity is an ownership or investment interest, for purposes of the exception, in such a case, HCFA also will apply the three above-referenced requirements to the first compensation arrangement with an unowned entity in the chain of relationships between the physician and the DHS entity.¹²⁶

Applying the elements of the indirect compensation arrangements exception to the referring physician/PT company/SNF example discussed above, provided that certain conditions (discussed below) are met, the arrangement will fit within the exception. Further, for purposes of this analysis, it should be assumed that (i) the per-service payments for the PT services furnished by the PT company to the SNF are assumed to be fixed (*i.e.*, will not vary) for the entire term of the written, signed agreement between the PT company and the SNF, which agreement describes

¹²⁴ See 66 Fed. Reg. at 866-87; commentary; 66 Fed. Reg. at 962 (42 C.F.R. §411.357(p)).

¹²⁵ Note that the language in this element is substantially identical to the language in 42 C.F.R. 411.354(d)(2), which describes the conditions under which compensation (including time-based or per unit-of-service based compensation) will not be deemed to take into account the volume or value of referrals.

¹²⁶ 66 Fed. Reg. at 867.

the PT services covered by the arrangement; (ii) the per-service rate is reasonably commensurate with the prevailing rate in the community for comparable PT services, was determined without reference to anticipated referrals to the SNF from, or other business generated for the SNF by, the PT company's owner (*i.e.*, the referring physician), and thus may be considered FMV; and (iii) the arrangement between the PT company and the SNF fits within the "leasing safe harbor" under the Anti-kickback Statute and otherwise is not violative of any other billing or claims submission-related laws. Based on these assumptions, the FMV element of the first, second (*i.e.*, signed, written agreement) and third prong (*i.e.*, compliance with the Anti-kickback Statute) of the exception are met. Whether or not the arrangement qualifies for the indirect compensation arrangements exception thus turns on whether the arrangement would be considered to take into account the value or volume of referrals or other business generated by the referring physician for the DHS entity (in this case, the SNF). Because the referring physician has an ownership interest in the directly compensating entity (in this case, the PT company), this analysis focuses on the first compensation arrangement in the chain of financial relationships between an owned entity and an unowned entity (in this case, the agreement between the PT company and the SNF). While the referring physician is considered to have an indirect compensation arrangement with the SNF because payments to the PT company from the SNF, in HCFA's view, "otherwise reflect" the volume or value of the referring physician's referrals to the SNF (*i.e.*, insofar as his referrals to the SNF resulted in business for the PT company which he owns), these payments (*i.e.*, which, for our example, are assumed to be fixed, FMV per-service units of compensation that remain in effect without modification during the term of the agreement) will not be considered to "take into account the volume or value of referrals or other business generated by the referring physician." As illustrated by this example, the fact that an arrangement is determined to be an indirect compensation arrangement does not mean that referrals by the referring physician to the DHS entity will be prohibited insofar as the distinction between the "otherwise reflects" and "takes into account" standards may, depending on the circumstances, permit the arrangement to qualify for the indirect compensation arrangements exception.

G. GROUP PRACTICE ARRANGEMENTS¹²⁷

A group must meet the following nine standards to constitute a group practice: (i) the group must be organized as a single legal entity; (ii) the group must have two or more physician members (*i.e.*, employees or direct or indirect owners); (iii) each member of the group must furnish substantially the full range of patient care services he or she routinely furnishes in practice and do so through joint use of shared office space, facilities, equipment and personnel (*i.e.*, shared within the group); (iv) with two limited exceptions (for groups in HPSAs and new group practices in a 12 month start-up period), substantially all (*i.e.*, 75%) of the total patient care services provided by group practice members must be provided through the group practice and billed under a billing number assigned to the group and the amounts received must be treated as receipts of the group (this is an average focused on the services of the physicians in any setting and as a default measure it is based on actual time spent); (v) the group's compensation methodology determined in advance; (vi) the group practice must be a unified business; (vii) no member of the group may be compensated directly or indirectly based on the value or volume of referrals except for permitted productivity bonuses; (viii) members of the group (*i.e.*, excluding independent contractors) must personally conduct at least 75% of the physician-patient

¹²⁷ 42 C.F.R. §411.352.

encounters of the group practice (the second 75% standard); and (ix) profit sharing and productivity bonuses of group members may be indirectly (but not directly) related to the volume or value of referrals for DHS performed by others (if self-performed, it would not be a "referral") and may be determined based on personally performed services performed by the physician (including services "incident to" such personally performed services). These standards generally track the statute and the thrust of the Proposed Regulations but with added flexibility in terms of subpooling (discussed below) and determining productivity bonuses, as well as the elimination of the group practice attestation requirement.

Many of the questions surrounding the group practice definition have been answered favorably in the Phase I Final Regulations, but other questions and a few challenges remain. Perhaps the most significant challenge will be for hospitals that have employed physicians without creating a separate clinic corporation or so called captive or friendly PC – those unincorporated physician groups would not be able to qualify as group practices under the Phase I Final Regulations even though their counterparts in a captive or friendly PC could qualify.¹²⁸

1. Ownership and Legal Organization Requirements

1.1. What is the significance of changing "separate legal entity" to "single legal entity"? One lingering question from the Proposed Regulations was whether an unincorporated division of a hospital can be a group practice and, if so, whether a hospital can have multiple group practices that are unincorporated divisions? Unfortunately, HCFA appears to have answered both questions in the negative. In Section 411.352(a), HCFA states that a "group practice must consist of a single legal entity formed primarily for the purpose of being a physician group practice." (Emphasis added). Because a hospital corporation is arguably formed primarily for the purpose of owning and operating a hospital facility, it appears that physicians employed directly by a hospital can not constitute a group practice under any circumstances under the new regulations. HCFA confirmed that interpretation in the preamble, stating that "a hospital that employs physicians is not a 'group practice' for purposes of Section 1877 of the Act, although the hospital can form or acquire a group practice that is a separate single legal entity."¹²⁹ HCFA also noted that it "would stretch the meaning of a 'group practice' too far" to interpret the term as including hospital-employed physicians either as a single group or multiple groups.¹³⁰

1.1.1. This interpretation also suggests that an entity originally organized for a different purpose can not be converted to a group practice – a technique often used by tax-exempt organizations to change their primary purposes from one exempt activity to another without having to reapply to the IRS for recognition of tax-exempt status.

1.1.2. The Phase I Final Regulations also state that "a single legal entity does not include informal affiliations of physicians formed substantially to share

¹²⁸ 66 Fed. Reg. at 898-99. 903.

¹²⁹ 66 Fed. Reg. at 897.

¹³⁰ 66 Fed. Reg. at 898-99.

profits from referrals."¹³¹ The regulations do not define "substantial purpose" in this context. HCFA did note, however, that it was Congress' intent to confer group practice status only on bona fide group practices and not "loose confederations of physicians who come together as a 'group' substantially in order to capture the profits of DHS under the in-office ancillary services exception."¹³² HCFA noted that so-called "group practices without walls" fall into the "loose confederation" category and would not be group practices for purposes of the Stark Law.¹³³

1.2. The Phase I Final Regulations reinforce that a hospital (or a solo physician PC) can own a group practice – so long as the group practice is a separate entity meeting the "single entity" standard. HCFA also acknowledged that hospitals and physicians may jointly own group practices and that a physician-directed clinic may qualify as a group practice.¹³⁴ A solo physician PC or a partnership with one physician and one nonphysician partner wanting to qualify as a group practice could do so provided the PC also employs at least one other physician (in the case of a PC, the preamble states the physician must be a full-time employee).¹³⁵ This is an apparent change from the Proposed Regulations, wherein HCFA noted that a group practice organized as a partnership must include at least two physicians as partners and a group practice organized as a PC must include at least two physicians incorporated together.¹³⁶ HCFA does note, however, that if the PC is a captive or friendly PC where the physician owner does not practice medicine in the PC, then the PC must employ at least two physicians to qualify as a group practice and the physician owner himself or herself would not be treated as a member of the group for any purpose.¹³⁷

1.3. A solo PC can own a group practice so long as the solo PC is not an active medical practice. The Phase I Final Regulations specify that a group practice "may not be organized or owned (in whole or in part) by another medical practice that is an operating physician practice (regardless of whether the medical practice meets the conditions for a group practice under this section)."¹³⁸ HCFA indicated that the restriction on members not being entities with an active medical practice is intended to preclude existing groups from banding together to form a group practice primarily to share referrals for in-office ancillary services.¹³⁹ Likewise, hospitals or other entities that own multiple group practices can not treat them as a single group practice (such as for purposes of the in-office ancillary services exception) merely because they are "under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization."¹⁴⁰

¹³¹ 42 C.F.R. §411.352(a); 66 Fed. Reg. at 956.

¹³² 66 Fed. Reg. at 875.

¹³³ 66 Fed. Reg. at 897.

¹³⁴ 66 Fed. Reg. at 899.

¹³⁵ 66 Fed. Reg. at 897.

¹³⁶ 63 Fed. Reg. at 1687.

¹³⁷ 66 Fed. Reg. at 903.

¹³⁸ 42 C.F.R. §411.352(a); 66 Fed. Reg. at 956

¹³⁹ 66 Fed. Reg. at 897.

¹⁴⁰ 42 C.F.R. §411.352(a); 66 Fed. Reg. at 899, 956.

2. Unified Business

The Phase I Final Regulations continue the requirement that a group practice be a unified business. Unlike the Proposed Regulations, the Phase I Final Regulations include the following specific requirements: (i) centralized decision-making, which must be exercised "by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries)"; (ii) consolidated billing, accounting and financial reporting; and (iii) centralized utilization review.¹⁴¹ HCFA does not specify what a representative body means in this context (e.g., does it require a majority physician board or at least physician control of economic decisions – if so, that may conflict with exemption standards).

2.1. Group-wide UR. The centralized utilization review would be satisfied, for example, if utilization review is conducted on a group-wide basis.¹⁴²

2.2. Unified Business for All Sources of Revenues. In assessing the "unified business" requirement, HCFA will look at whether there is centralized determination of physician compensation derived from all sources, not just the provision of DHS.¹⁴³ Subpooling methods described below in the discussion of productivity compensation (e.g., by specialty or location) also will be measured against the three components of the unified business standard described above. For this purpose, HCFA will consider the group's method of distributing revenues from all sources, not just DHS. HCFA acknowledges that groups can distribute revenues from services that are not Medicare (or Medicaid) DHS in any manner they wish; however, those methods must indicate that the group practice is a unified business for more than just the provision of DHS.¹⁴⁴

2.3. Opt Out. Some physicians in a group may elect to opt out of the Medicare program. Those physicians, provided they do not receive payments from the Medicare program, would not be bound by the Stark Law and, therefore, could refer to entities with which they have a financial relationship. Such physicians still can be members of the group for periods in which they provide services to group patients that are billed through the group practice to payors other than Medicare. Any services he or she bills in his or her own name, however, would not be group services and would be excluded from the "substantially all test" for patient care services.¹⁴⁵

3. Use of Independent Contractor Physicians

3.1. The definition of "member of the group" has been revised to include not only physician employees of the group practice but also physicians who own an equity interest through either a PC or another entity (the Proposed Regulations limited indirect ownership to an individual PC) and to provide that the physician need not be employed directly by the group practice if he or she is an employee of his/her individual PC and

¹⁴¹ 42 C.F.R. §411.352(f)(1)(i)-(iii); 66 Fed. Reg. at 957.

¹⁴² 66 Fed. Reg. at 906.

¹⁴³ 66 Fed. Reg. at 875.

¹⁴⁴ 66 Fed. Reg. at 907.

¹⁴⁵ 66 Fed. Reg. at 902.

that PC owns an equity interest in the group practice. Although HCFA has deleted the express reference to full-time or part-time status from the Proposed Regulations, the definition still appears to contemplate part-time employees by referring to the time spent furnishing patient care services to the group. The Phase I Final Regulations also would effectuate the Proposed Regulations' intended exclusion of independent contractors from being members of the group (unless they are direct or indirect owners of the group) and would also exclude leased employees. Both on-call physicians and locum tenens physicians, however, could be members of the group.¹⁴⁶

3.2. HCFA also added a definition of "physician in the group practice" that includes members of the group and, in certain circumstances, independent contractors. The new regulations provide that an independent contractor physician will be included as a "physician in the group practice" only during the time he or she is furnishing patient care services to the group practice under a contractual arrangement with the group to provide services to the group's patients in the group's facilities. Furthermore, to fit within this definition, the contract must include the same restrictions on compensation that apply to members of the group practice under Section 411.352(g) of the regulations (or the personal services exception of Section 411.357(d)) and it must comply with the reassignment rules. The definition also expressly states that "[r]eferrals from an independent contractor who is a physician in the group are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b)."¹⁴⁷

4. "Substantially All" Test

4.1. 75% Standard. The Phase I Final Regulations retain the "75% of patient care services" standard for the "substantially all" test, but do provide additional guidance and flexibility on how to measure the amount of patient care services provided and add a new exception for groups in a start-up phase.

4.2. Patient Care Services. "Patient care services" are defined as any tasks performed by a physician within the group practice that address the medical needs of specific patients or patients in general, whether or not they involve direct patient encounters or generally benefit the practice. As such, the term includes, for example, the services of physicians who do not directly treat patients (e.g., time spent consulting with other physicians or reviewing laboratory tests, training staff members, arranging for equipment, or performing administrative or management tasks). In the preamble, HCFA also noted that patient care services include pro bono medical care (provided within the group but not as an outside volunteer activity).¹⁴⁸

¹⁴⁶ An on-call physician is one who provides on-call services for members of the group practice, and a physician may be on-call for one group and a member of another group. On-call physicians will be treated as members for the two 75% tests and supervision requirements of the in-office ancillary services exception if their services are billed by the practice for which they are serving on-call. 66 Fed. Reg. at 901. HCFA defines "locum tenens physician" with reference to the assignment rules set forth in Section 3060.7 of the Medicare Carriers Manual. 66 Fed. Reg. at 954. HCFA did observe that a new physician practicing on a "trial run basis" in the group would not be considered a locum tenens physician. 66 Fed. Reg. at 901.

¹⁴⁷ 66 Fed. Reg. at 955.

¹⁴⁸ 66 Fed. Reg. at 900 & 903.

4.3. Alternative Measurements. Groups may still measure these services on the basis of actual time spent by their members. The time-based method, however, would not be the exclusive approach to measuring substantiality. HCFA specifies that the required documentation for a time-based calculation can be "any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries)."¹⁴⁹ Groups also may use an alternative measure as long as it "is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented."¹⁵⁰ Examples of alternative methods that may be acceptable include personal schedules and billing records. In addition, the preamble notes that one commenter suggested using RVUs as the measure, something that while not mentioned specifically by HCFA may be subsumed within "billing records" – which was mentioned.¹⁵¹ Regardless of the method used, the Phase I Final Regulations specify that the group must make the supporting documentation available to HHS upon request, thus placing a premium both on documenting the level of services provided and on maintaining that documentation in an auditable form.¹⁵²

4.4. Global Billing. Group practices may count the professional component of services provided by member physicians under a global payment arrangement when calculating the patient care services 75% test even if the hospital bills Medicare directly, provided that the receipts are treated as receipts of the group. HCFA's rationale is that the requirement of billing under a billing number assigned to the group does not refer solely to a Medicare or Medicaid billing number.¹⁵³

4.5. HPSA. The HPSA exceptions are unchanged from the Proposed Regulations. The substantially all test would not apply to group practice located solely in a HPSA and, for groups located outside a HPSA, time spent by group members in a HPSA should not be counted in assessing compliance with the substantially all test.¹⁵⁴

4.6. New Groups. New group practices also get some relief under the Phase I Final Regulations. During a start-up period of up to twelve months from the date a group practice is formed, the group "must make a reasonable, good faith effort to ensure" that it will meet the substantially all test "as soon as practicable," but not later than twelve months after the group is formed. This special rule applies only to new group practices and not to existing groups that add one or more members or reorganize.¹⁵⁵ A merger of existing practices, however, may qualify for the special rule. In the preamble, in the context of discussion the single legal entity requirement for group practices, HCFA referred to the formation of a "new group practice" through the merger of existing group practices (stating that the predecessors need not dissolve so long as they cease operating as medical group practices).¹⁵⁶

¹⁴⁹ 42 C.F.R. §411.352(d)(1)(i); 66 Fed. Reg. at 957.

¹⁵⁰ 42 C.F.R. §411.352(d)(1)(ii); 66 Fed. Reg. at 957.

¹⁵¹ 66 Fed. Reg. at 904.

¹⁵² 42 C.F.R. §411.352(d)(2); 66 Fed. Reg. at 957.

¹⁵³ 66 Fed. Reg. at 905.

¹⁵⁴ 42 C.F.R. §411.352(d)(3)-(4); 66 Fed. Reg. at 957.

¹⁵⁵ 42 C.F.R. §411.352(d)(5); 66 Fed. Reg. at 957.

¹⁵⁶ 66 Fed. Reg. at 898.

5. Compensation Methodology

5.1. Non-DHS Revenues. The physician compensation provisions for group practices generally only affect distribution of DHS revenues (except for applying the "unified business" requirement discussed above where all compensation sources are relevant). HCFA also notes that DHS revenues likely constitute only a relatively small portion of the total revenues of most practices, though the preamble cites no support for that conclusion.¹⁵⁷ HCFA noted, however, that groups may find it difficult from a practical perspective to segregate DHS from other revenues.¹⁵⁸

5.2. Method Previously Determined. In the Phase I Final Regulations, HCFA clarifies the requirement for a group practice's compensation methodology to be set in advance. The Phase I Final Regulations specify that to qualify as a group practice, the group's income and overhead expenses must be distributed according to methods (*i.e.*, the compensation methodology) "that are determined before the receipt of payment for the services giving rise to the overhead expenses or producing the income." The Proposed Regulations were somewhat more restrictive by requiring that the compensation methodology be determined before the time period in which the income was earned or the expense incurred as opposed to focusing on the date of payment for services. HCFA makes clear in the preamble, however, that this is not a "prior to distribution" rule – in other words, by "prior to payment for services" the regulations mean prior to the group practice's receipt of payment from a third party not merely prior to payment of compensation to physicians in the group practice. Ad hoc distribution formulas established after any collections are received for the year would not be permitted. The Phase I Final Regulations also expressly allow for prospective adjustments in the compensation methodology as often as the group deems appropriate, subject to the limits on productivity bonuses.¹⁵⁹ It is not clear, however, what the regulatory effect would be of multiple prospective adjustments during the year, such as monthly for receipts that come in during that month.

5.2.1. HCFA rejected a proposal to make an exception for unexpected income.¹⁶⁰

5.2.2. HCFA acknowledged, however, that a group can compensate its physicians on different methodologies and still qualify as a unified business, at least in the case of larger groups that have expanded through acquiring other existing groups where the various compensation arrangements were negotiated in advance by the parties.¹⁶¹

5.3. Indirectly Related to DHS. One of the more difficult aspects of group practice formation and operation has been developing a compensation methodology that would not be directly or indirectly related to at least some degree to the volume or value of DHS referrals. In outlining general principles of physician compensation for purposes of the Stark

¹⁵⁷ 66 Fed. Reg. at 875, 908.

¹⁵⁸ 66 Fed. Reg. at 876.

¹⁵⁹ 42 C.F.R. §411.352(e); 66 Fed. Reg. at 905-06, 957

¹⁶⁰ 66 Fed. Reg. at 906.

¹⁶¹ 66 Fed. Reg. at 907.

Law, HCFA noted that "the Congress recognized that in the case of group practices, revenues derived from DHS must be distributed to the group practice members in some fashion, even though the members generate the DHS revenue." Nevertheless, in HCFA's view, Congress also sought "to minimize the economic incentives to generate unnecessary referrals of DHS" in a group practice. Accordingly, in the Stark Law, Congress permitted physicians in a group practice (including members and qualifying independent contractors) "to receive shares of the overall profits of the group, so long as those shares do not directly correlate to the volume or value of referrals generated by the member or 'physician in the group practice' for DHS performed by someone else." The Stark Law also permits group practices to pay productivity bonuses to their physicians "based directly on personal productivity (including services incident to personally performed services)," but it does not permit groups to pay their physicians "any productivity bonus based directly on referrals of DHS performed by someone else." The "incident to" services also must comply with the requirements of Section 1861(s)(2)(A) of the Social Security Act, including (i) direct supervision by a physician, which requires the physician to be present in the office suite and immediately available to provide assistance and direction; and (ii) the person providing the incident to services must be an employee of the physician or physician-directed clinic. HCFA noted, however, that it may revisit the issue of compensation being tied to incident to services if it finds that abuses are occurring, especially in physician-directed clinics. As described below, the Phase I Final Regulations include a description of certain methodologies and compensation practices that will be deemed to be only indirectly related to the volume or value of DHS referrals for purposes of the group practice provisions of the Stark Law and therefore allowable under the Stark Law. HCFA also noted that groups are free to develop their own indirect methodologies, which will be subject to review on a case-by-case basis.¹⁶²

5.3.1. It remains to be seen whether HCFA will apply the same logic to conclude that for employed physicians outside of a group practice the same level of indirect relationship should be acceptable – *i.e.*, too indirect to be indirect. For group practices, HCFA dealt with the issue by removing the "or indirect" limitation. That "or indirect" limitation is included in the statutory language for the employee exception, but not the personal services arrangement exception.

5.3.2. The personal services arrangement exception does include a restriction that the compensation (except for managed care organizations' physician incentive plans) not take into account "referrals or other business generated between the parties." HCFA, in the Proposed Regulations, proposed adding that same "or other business" limitation to the employee exception; however, it was not included in the statute.

5.3.3. In the Proposed Regulations, these nuances were complicated by HCFA's statement that it would imply the "directly or indirectly" and "other business generated" restrictions wherever the volume or value standard appeared in the Proposed Regulations, whether or not either phrase was expressly mentioned.¹⁶³ It is not totally clear whether HCFA's change in the volume or

¹⁶² 66 Fed. Reg. at 876, 909.

¹⁶³ 63 Fed. Reg. at 1699-1700.

value standard suggests that the employee and personal services exceptions will be further revised in the Phase II Final Regulations to expressly add or retain the "directly or indirectly" and "other business generated" restrictions or whether HCFA will defer to the literal wording of the statute and omit those additional standards.

5.3.4. The phrase "or other business generated"¹⁶⁴ is discussed in the volume or value standard discussion.

5.4. Pooling by Specialty or Location (Subpooling). The Phase I Final Regulations preserve the same basic phrasing of the productivity/profit sharing bonus provisions, though the application and exceptions (or safe harbors) result in a significant liberalization of the rules. The general standard continues to be that physicians in a group practice (members and qualifying independent contractors) may be paid a share of the group's overall profits or a productivity bonus based on personally performed services (or services incident to those personally performed services). "provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician."¹⁶⁵ The Phase I Final Regulations provide more flexibility for the incentive compensation plans of group practices by liberalizing the prohibition on subpooling by location or specialty and using cost- or location-based accounting. Revenues from non-DHS may be subpooled without restriction under the Stark Law. The Phase I Final Regulations also provide for subpooling of revenues from DHS under the special rule for productivity bonuses.¹⁶⁶ The Phase I Final Regulations include quasi-safe harbors covering distributions of profit sharing and bonus payments that will satisfy the volume or value standard.

5.4.1. Overall Profits Methodology. The Phase I Final Regulations substantially reduce the restrictions on subpooling in part by defining "overall profits" as the entire profits from DHS payable by Medicare or Medicaid derived by either the group as a whole or any component of the group consisting of at least five physicians. Accordingly, a local office or specialty group of at least five physicians could be treated as a separate profit center for purposes of paying profit sharing amounts and the group still could qualify as a group practice. (The regulations do not specify a full-time service requirement for the five physicians.) Those profits may be divided only in a manner that satisfies the volume or value standard, and meeting any one of the following four conditions would qualify under the Phase I Final Regulations: (i) divided per capita (e.g., based on the number of members or physicians in the group); (ii) the Medicare/Medicaid DHS revenues are distributed based on the distribution of the group's "revenues attributed to services that are not DHS payable by any Federal health care program or private payer"; (iii) revenues from DHS constitute less than 5% of the group's total revenues and the portion thereof allocated to each physician in the group constitutes 5% or less of his/her total compensation from the group; or (iv) a reasonable cause catch-all – "[o]verall profits are divided in a reasonable

¹⁶⁴ 66 Fed. Reg. at 876

¹⁶⁵ 42 C.F.R. §411.352(f)(2); 66 Fed. Reg. at 957.

¹⁶⁶ 42 C.F.R. §411.352(f)(2); 66 Fed. Reg. at 957.

and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS." That last clause introduces another element of subjectivity or intent into the Stark Law compliance scenario.¹⁶⁷ There is no mention of RVUs as a permissible (or specifically impermissible) factor in allocating profits, though HCFA did note in the preamble that some commenters suggested RVUs as a basis for dividing profits that would not be even indirectly related to the volume or value of referrals.¹⁶⁸ HCFA did, however, state as its goal assuring that the subpooling does not allocate compensation in a manner "directly related to the volume or value of the physician's referrals."¹⁶⁹ The loosening of the restrictions on subpooling may result in more multi-specialty or multi-site groups because of the removal of impediments for varying compensation methodologies or pools among specialists or multiple locations in many circumstances.

5.4.2. Productivity Bonus Methodologies. Similar safe harbors apply for productivity bonuses, though there is no five physician minimum. A productivity bonus for personally performed services (and services incident to such personally performed services) would satisfy the volume or value standard if it is determined in a manner that meets any one of the following four conditions under the Phase I Final Regulations: (i) bonus based on physician's total patient encounters or relative value units (RVUs); (ii) bonus based on the allocation of physician compensation attributable to services other than DHS payable by any Federal health care program or private payer; (iii) revenues from DHS constitute less than 5% of the group's total revenues and the portion thereof allocated to each physician in the group constitutes 5% or less of his/her total compensation from the group; or (iv) a reasonable cause catch-all – "[t]he bonus is calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS."¹⁷⁰ The reference to RVUs as a basis for determining productivity bonuses removes the uncertainty caused by possible inclusion of some DHS in what is accounted for in the RVUs and at the same time, likely because of the express inclusion of RVUs, HCFA noted that the parenthetical statement at 63 Fed. Reg. 1691 "such as value based on complexity of the service" is no longer relevant to the Phase I Final Regulations.¹⁷¹

5.4.3. Documentation. In each case, supporting documentation verifying the method used to calculate the profit shares or bonuses and the resulting amount of compensation must be made available to the HHS upon request. Moreover, if a group relies on the catch-all provisions rather than the express safe harbors, in HCFA's words, "the group practice essentially bears the risk of noncompliance."¹⁷²

¹⁶⁷ 42 C.F.R. §411.352(i)(2); 66 Fed. Reg. at 957.

¹⁶⁸ 66 Fed. Reg. at 909.

¹⁶⁹ 66 Fed. Reg. at 895.

¹⁷⁰ 42 C.F.R. §411.352(i)(3); 66 Fed. Reg. at 957.

¹⁷¹ 66 Fed. Reg. at 910.

¹⁷² 42 C.F.R. §411.352(i)(4); 66 Fed. Reg. at 910, 957.

5.4.4. Capitation Payments. HCFA noted in the preamble to the Phase I Final Regulations that it believes capitation payments are unlikely to lead to increased utilization. Accordingly, "[p]arties may use any reasonable allocation method with respect to such payments."¹⁷³

5.5. These compensation methodology provisions suggest a number of unanswered questions. For example, what effect does the elimination of the concept of a solo physician self-referral have on the range of permitted compensation methodologies for hospital-employed physicians? Can they be treated the same as solo practitioners for purposes of the Stark Law? How does that square with the revised productivity bonus provision for defining a group practice (which suggests self-referred designated health services can not be considered in a group practice setting) – is this the trade-off to equalize group and non-group settings and/or conform the solo practice rules to reality?

6. Exceptions for Compensation

There is no group practice exception per se, rather qualifying as a group practice provides more flexibility under the in-office ancillary services exception and allows physicians to take advantage of the physician services exception. Nevertheless, HCFA noted that if a physician is a member of a group practice (likely intended to say "physician in a group practice" instead), "his or her compensation need only comply with the group practice rules." Referrals are then allowed in accordance with the physician services and in-office ancillary services exceptions. HCFA acknowledged, however, that "nothing prevents a physician and group practice from using the employee exception instead."¹⁷⁴ What that commentary leaves open to question is whether the employee exception can be "stacked" on top of the in-office ancillary services exception for other referrals either for a group practice or other physicians.

7. Faculty Practice Plans

The Phase I Final Regulations deleted the special provision regarding certain pre-existing arrangements with faculty practice plans and replaced it with a new Academic Medical Center exception described below.

8. Attestation

HCFA has deleted the group practice certification requirement.¹⁷⁵ Under the certification provision, there was a possibility that an incorrect interpretation of or failure to meet the tests could give rise to a false claims exposure (through falsely certifying that the physicians constituted a group practice and therefore were billing in compliance with the Stark Law). Deletion of the certification provision effectively allows physicians to argue for group practice status in the alternative and eliminates that potential false claims exposure. HCFA did state, however, that it intends to develop a streamlined reporting system to build a sufficient audit trail

¹⁷³ 66 Fed. Reg. at 910.

¹⁷⁴ 66 Fed. Reg. at 910.

¹⁷⁵ 66 Fed. Reg. at 856.

of particular relationships to ensure that the relationships qualify for exceptions, including the ability to demonstrate qualification as a group practice where relevant.¹⁷⁶

H. SERVICE EXCEPTIONS RELEVANT TO GROUP PRACTICES¹⁷⁷

1. Physician Services

1.1. Under this exception, the referral prohibition does not apply to physician services that are furnished personally by, or under the supervision of, another physician who is a member of the same group practice as the referring physician or who is physician in the group practice.¹⁷⁸

1.2. The Phase I Final Regulations accommodate the exclusion of independent contractors from membership in group practices by revising the physician services exception to apply to services provided by or under the supervision of a member or other physician in the same group practice as the referring physician. The Phase I Final Regulations also incorporate compliance with other applicable Medicare supervision requirements as part of the physician services exception. HCFA also specified that for purposes of this exception, physician services includes only those incident to services that are physician services under Section 410.20(a) of the regulations – all other incident to services (e.g., diagnostic tests, physical therapy) are excluded.¹⁷⁹

1.3. HCFA notes in the preamble that the physician services exception is of limited application. Although it allows physicians within group practices to refer to other physicians in the group, it does not include services performed by the referring physician (though they likely would not be the result of a "referral" under the new definition).¹⁸⁰ Likewise, the exception does not cover "incident to" services unless performed by the physician receiving the referral.¹⁸¹

1.4. One commenter requested a specific exception for professional reads of various diagnostic procedures (e.g., EKG, pulmonary function testing, EEG). According to HCFA, the specific examples listed "typically will not be DHS" and for services that are DHS, either the physician services or in-office ancillary services exception may apply. Finally, if the physician is in a group practice, those definitional rules will apply and, subject to those rules, the physician performing the read may be paid directly based on his personal performance of that professional service.¹⁸²

1.5. HCFA refused to extend the physician services exception to services performed by a nonphysician for fear that it would allow providers to circumvent the requirements of the in-office ancillary services exception. HCFA did, however, specifically ask

¹⁷⁶ 66 Fed. Reg. at 911.

¹⁷⁷ 42 C.F.R. §411.355

¹⁷⁸ 42 C.F.R. §411.355(a); 66 Fed. Reg. at 959.

¹⁷⁹ 42 C.F.R. §411.355(a); 66 Fed. Reg. at 959.

¹⁸⁰ 66 Fed. Reg. at 879.

¹⁸¹ 66 Fed. Reg. at 880.

¹⁸² 66 Fed. Reg. at 880.

for comments on "the need for a further exception for referred DHS performed by nonphysician practitioners in a group practice setting."¹⁸³

1.6. HCFA continues to define physician services with reference to general Medicare usage under Section 1861 of the Act.

2. In-office Ancillary Services

HCFA added a significant degree of detail to the in-office ancillary services exception, building on the existing requirements.¹⁸⁴ In HCFA's view, the exception is generally "broader and administratively simpler than the proposed exception"; however, HCFA did state that it has substantially limited the ability of group practices to use part-time arrangements to provide DHS at locations where the group does not routinely provide a wide range of services other than Federal or private pay DHS. In revising the exception, HCFA considered three key principles: (i) that Congress was concerned with regulating ordering DHS even within a group practice; (ii) that Congress intended to protect some in-office ancillary services if they were truly ancillary to the medical services being provided by the physician or group; and (iii) that the boundaries Congress intended were best expressed in the location requirement of the in-office ancillary services exception. HCFA also noted that "referrals – in-office or otherwise – for services that are not DHS need not fit in the exception, since they do not implicate the statute."¹⁸⁵

2.1. Scope of Exception. Under this exception, the referral prohibition does not apply to certain ancillary services (excluding all but certain specific items of DME) that are (i) personally performed or supervised – *i.e.*, furnished personally by the referring physician or another physician member of the same group practice, or furnished under the supervision of the referring physician or another physician in the same group practice (*i.e.*, members and certain independent contractors); (ii) furnished in a qualifying location – *i.e.*, the same building (though potentially a different part of the building) as the referring physician or other group member furnishes substantial physician services unrelated to the furnishing of DHS (Medicare, Medicaid or private pay) even if they lead to the ordering of DHS or a centralized building used by the group practice for the provision of some or all of its clinical laboratory services or other DHS; and (iii) billed as group practice services – *i.e.*, billed by the physician performing or supervising the service, by the group practice under a number assigned to the group, by an entity wholly owned by the group under the entity's own billing number or one assigned to the group or the physician, or a third party independent billing company as agent.

2.2. Personally Provided. The Phase I Final Regulations partially accommodate the exclusion of independent contractors from membership in group practices by revising the in-office ancillary services exception to apply to services provided by or under the supervision of the referring physician or another member of the same group practice or under the supervision of another physician in the same group practice (which can include an independent contractor). The exception does not, however, apply to in-office ancillary services that are

¹⁸³ 66 Fed. Reg. at 880.

¹⁸⁴ 42 C.F.R. §411.355(b); 66 Fed. Reg. at 959-60.

¹⁸⁵ 66 Fed. Reg. at 881.

performed by an independent contract physician in the group practice unless he or she is the referring physician.

2.2.1. Independent Contractors. If the referring physician is an independent contractor who is a physician in the group practice, the same building location requirement must be met because the centralized building option only applies to referrals by members of the group practice.¹⁸⁶

2.2.2. Supervision. HCFA has deleted the separately defined direct supervision requirement in favor of simply following other Medicare rules for supervision of ancillary services in an office setting. What is the significance of the deletion of the definition of "direct supervision"? HCFA noted that it is broadly interpreting "supervision" in this context to be consistent with the general supervision requirements for the Medicare program for such services.¹⁸⁷ (In that regard, note that HCFA recently revised various conditions of participation related to anesthesia services in order to allow CRNAs to administer anesthesia without physician supervision where state law permits.)¹⁸⁸

2.2.3. Laboratory Subsidiary. The ancillaries need not be provided through the same entity that employs the physicians. In the Phase I Final Regulations, HCFA also clarified that a group practice can itself own one or more subsidiaries for purposes of providing services to the group practice.¹⁸⁹ HCFA also reiterated its view (from an example in the preamble to the Stark I Final Rules) that "a group practice could wholly own and separately incorporate a laboratory facility that provides laboratory services to a group practice or other patients." HCFA goes on to note that in that example, the physicians in the group practice could qualify for the in-office ancillary services exception with respect to those laboratory services if they meet the supervision, location and billing requirements.¹⁹⁰ In the original example from the 1995 Stark I Final Rules, HCFA went on to note that the in-office ancillary services exception "does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided." By way of analogy, HCFA noted that the billing requirement contemplates an entity wholly-owned by the group practice doing the billing. In HCFA's view, this aspect of the billing requirement shows that the exception "appears to anticipate that a 'group practice' . . . may wholly own separate legal entities for billing or for providing ancillary services."¹⁹¹

2.3. Location. The location requirement for where ancillary services are furnished has been liberalized in some respects (opening up more areas in a building) and

¹⁸⁶ 66 Fed. Reg. at 887.

¹⁸⁷ 66 Fed. Reg. at 885.

¹⁸⁸ 66 Fed. Reg. 4674 (Jan. 18, 2001).

¹⁸⁹ 42 C.F.R. §411.352(a); 66 Fed. Reg. at 899, 956-57.

¹⁹⁰ 60 Fed. Reg. 41913, 41936 (Aug. 14, 1995); 66 Fed. Reg. at 899.

¹⁹¹ 60 Fed. Reg. at 41936.

restricted in others (as to the other services that must be provided in the same location) in the Phase I Final Regulations.

2.3.1. Same Building. HCFA also added a definition of "same building," meaning a structure that has (or a group of structures that share) a single street address as assigned by the U.S. Postal Service. It includes only usable professional office space and common areas (e.g., lobbies, corridors, elevator banks and restrooms) and excludes all exterior spaces (e.g., lawns, courtyards, driveways, parking lots), interior parking garages, mobile vehicles, vans and trailers.¹⁹² For example, a van that is "rented serially" by a number of group practices or physicians and circulates among their offices would not be considered the "same building"; however, other exceptions such as the rural provider exception may protect the arrangement in a rural area.¹⁹³

HCFA describes the mailing address rule as a bright line rule that will be easy to apply and produce fair results in a vast majority of cases; however, HCFA acknowledges that it "may result in an occasional anomaly." For example, suites used by the same group practice or solo physician in buildings with different street addresses would be treated as separate buildings.¹⁹⁴ The "same building" standard includes a substantial physician services test, a full range of services test and a primary nexus test. The intent is to pick up ancillary services that are truly ancillary to the physicians core medical practice and provided in the same location where those core medical services are routinely delivered rather than only token physician services that are not related to the furnishing of Federal or private pay DHS. HCFA also noted in the preamble that the space in the building where DHS are provided does not have to be adjacent to the space in which services unrelated to DHS are provided.¹⁹⁵

2.3.2. Substantial Services Test. For the decentralized or non-group practice provision of ancillary services, the services must be furnished in the same building, "but not necessarily in the same space or part of the building" in which the referring physician (or another member of the same group practice – *i.e.*, not including independent contractors) "furnishes substantial physician services" unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer or a private payer even if the unrelated services may result in the ordering or referral of DHS. (Emphasis added.) The preamble and the Phase I Final Regulations do not define what is substantial in this context. Substantiality and the reference to private pay DHS are new requirements not included in the Proposed Regulations.

2.3.3. Full Range of Services Test. Those unrelated physician services also must represent substantially the full range of physician services unrelated to

¹⁹² 66 Fed. Reg. at 890, 956.

¹⁹³ 66 Fed. Reg. at 891.

¹⁹⁴ 66 Fed. Reg. at 889

¹⁹⁵ 66 Fed. Reg. at 888.

the provision of DHS that the referring physician routinely furnishes in his or her practice or, if a member of a group practice, that he or she routinely provides for the group practice.

2.3.4. Primary Nexus Test. Finally, the receipt of DHS (regardless of whether paid by a federal program or private payer) must not be the primary reason that the patient comes in contact with the referring physician or his/her group practice. The preamble does not provide any examples of how one determines the "primary reason" – rather, HCFA describes it as a nexus test, that the patient's "primary nexus with the referring physician" should be the receipt of services that are unrelated to the provision of DHS. This appears to be another facts and circumstances standard. For example, HCFA notes that a physician providing physician services and DHS for his or her patients in a nursing home could not merely "provide token physician services to other nursing home patients in order to provide" those patients with DHS under the in-office ancillary services exception.¹⁹⁶ The difficulty in applying this test is in determining the point at which the relevant "referral" occurs. For example, if Physician A, a solo practitioner, refers a patient to unrelated Group Practice B for PT services and Physician C in that group prescribes a plan of care with a physical therapist employed by the group, is the referring physician A or C or both? If it is A, the same building standard may be satisfied but not if it is C. The definition of referral is broad enough to suggest that both are referring physicians, even though that may not be the result HCFA intended under the primary nexus test.

2.3.5. Independent Contractors. The activities of independent contractors do not count in measuring the substantial physician services test or the full range of services test unless the independent contractor is the referring physician.¹⁹⁷

2.4. Centralized Building. In the alternative, the ancillary services may be provided in a centralized building used by the group practice for the provision of some or all of the group's clinical laboratory services, or a centralized building used by the group practice for the provision of some or all of the group's DHS other than clinical laboratory services. Under the Proposed Regulations, group practices could have maintained only one centralized location for all DHS other than laboratory services. The Phase I Final Regulations instead allow a separate location for each non-laboratory DHS. HCFA also confirmed that a group practice may have more than one centralized building for the provision of DHS.¹⁹⁸

2.4.1. HCFA defined "centralized building" as including "all or part of a building." For this purpose, a building includes a mobile unit, but only if owned or leased on a full-time basis by and used exclusively by a group practice, 24/7 for a term of at least 6 months. The definition also notes that "[s]pace in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and

¹⁹⁶ 66 Fed. Reg. at 888. 890.

¹⁹⁷ 66 Fed. Reg. at 890.

¹⁹⁸ 66 Fed. Reg. at 892.

another provider (for example, a diagnostic imaging facility) is not a centralized building."¹⁹⁹

2.4.2. HCFA interprets the centralized building standard of the in-office ancillary services exception as including an exclusivity requirement. According to HCFA, the group must "own or lease and use the space exclusively on a full-time basis" to meet the centralized building standard.²⁰⁰ A group practice may have more than one centralized building. A group practice also may provide services to other providers from the mobile unit (e.g., purchased diagnostic tests) in the group practices centralized building.²⁰¹

2.4.3. The centralized building standard's exclusivity and minimum lease term aspects also preclude part-time centralized arrangements, such as where a group rents an MRI facility one day per week.²⁰² HCFA acknowledged that a group practice may lease or sublease a DHS facility to or from another group practice or solo practitioner on a part-time basis, however, DHS provided to the patients of the part-time lessee or sublessee group practice must meet the "same building" standard to qualify for the in-office ancillary services exception.²⁰³ HCFA's example does not specify whether the lessor or sublessor group practice still could meet the centralized building standard at that same location, but other commentary suggests that HCFA would view it as a shared facility falling under the same building standard.

2.5. Shared Facilities. HCFA interprets the same building component of the in-office ancillary services exception as protecting "shared DHS facilities, so long as the physicians or groups that share the facility also routinely provide their full range of services in the same building."²⁰⁴ The centralized building standard would not apply because shared facilities would not meet the "exclusively used requirement."

2.5.1. In order to take advantage of shared facilities in the same building, physicians or groups must comply with the supervision, location and billing requirements of the in-office ancillary services exception. HCFA declined to create a separate or broader shared facilities exception.²⁰⁵ In that regard, HCFA noted that the building rules were intended to allow physicians and groups a meaningful opportunity to provide bona fide in-office ancillary DHS to their patients while at the same time preventing groups "from using the in-office ancillary services exception to operate enterprises that are functionally nothing more than self-referred DHS enterprises, providing minimal services that are not DHS so as to comply nominally with the exception and capture DHS profits."

¹⁹⁹ 66 Fed. Reg. at 952,953.
²⁰⁰ 66 Fed. Reg. at 881.
²⁰¹ 66 Fed. Reg. at 952,953.
²⁰² 66 Fed. Reg. at 889, 892.
²⁰³ 66 Fed. Reg. at 889.
²⁰⁴ 66 Fed. Reg. at 881.
²⁰⁵ 66 Fed. Reg. at 888, 890 & 893.

2.5.2. HCFA also notes that in certain circumstances, part-time physicians could share the DHS facility if "they are also providing medical services they routinely provide that are not DHS (whether Federal or private pay)." On the other hand, part-time, intermittent arrangements that are no more than shared off-site facilities would not be protected. HCFA believes many such arrangements are created by physicians for the principal purpose of capturing revenue rather than enhancing patient care. In one of the few direct statements of how HCFA will interpret the Phase I Final Regulations prior to their technical effective date, HCFA stated that "[t]o the extent the January 1998 Proposed Regulation would have permitted these arrangements, it is no longer operative."²⁰⁶

2.6. Location of DHS. The Phase I Final Regulations specify that DHS will be treated as furnished at the location where the service is actually performed on the patient or the item dispensed to the patient in a manner sufficient to satisfy applicable Medicare payment and coverage rules.²⁰⁷ (It is unclear what criteria HCFA would apply in the same building location standard of the in-office ancillary services exception to determine where private pay DHS were provided.)

2.6.1. Patient Homes. For home health services provided by a physician whose principal practice consists of treating patients in their homes (not including a nursing home or other facility), the location requirement will be met if the referring physician or an accompanying nurse or technician provides the DHS contemporaneously with a physician service that is not a DHS provided by the referring physician.²⁰⁸ The references to DHS suggests that all DHS are included in the exception except for those specifically excluded. Under this provision, a building could include a patient's home if it satisfies the other requirements for a "centralized building" or the "same building."²⁰⁹ HCFA did, however, solicit comments on problems faced by traveling practitioners who provide services principally in patients' homes and may be disadvantaged by the location requirement.²¹⁰

3. Billing

The services must be billed by the physician performing or supervising the service, the group practice under a billing number assigned to the group (both for members and independent contractor physicians in the group), by an entity that is wholly owned by the physician or group practice under that entity's own billing number or one assigned to the physician or group practice, or by an independent third party billing company acting as an agent of one of the foregoing under a billing number assigned to the physician, group practice or subsidiary entity provided that the billing arrangement meets the requirements of Sections 424.73(b)(3) and 424.80(b)(6) of the regulations for payments to an agent of the supplier (*i.e.*, agency agreement

²⁰⁶ 66 Fed. Reg. at 881.

²⁰⁷ 42 C.F.R. §411.354(b)(5); 66 Fed. Reg. at 960.

²⁰⁸ 42 C.F.R. §411.354(b)(6); 66 Fed. Reg. at 960.

²⁰⁹ 66 Fed. Reg. at 888.

²¹⁰ 66 Fed. Reg. at 891.

with the provider, agent's compensation unrelated to amount billed or collected, provider may alter or revoke payment disposition instructions at any time and the agent acts solely on behalf of the provider in receiving payment). The Phase I Final Regulations also specify that for purposes of this requirement, a group practice may have and bill under multiple Medicare billing numbers subject to any applicable Medicare program restrictions.

3.1. Joint Ventures. HCFA cautioned that if practitioners form a separate joint venture to provide DHS in shared facilities, they may not be able to comply with the billing requirements if the joint venture does the billing because the joint venture would not be a wholly owned entity and, therefore, would not fit any of the billing categories for the in-office ancillary services exception.²¹¹ The unstated implication is that these joint ventures also would not qualify as independent third party billing companies. A joint venture, however, presumably could hire its own independent billing company.

4. Ancillary Services Covered

The ancillary services covered by this exception includes DME as well as other items and services, but only a limited variety of DME items. Infusion pumps are included, other than external ambulatory infusion pumps. Parenteral and enteral nutrients, equipment and supplies and related infusion pumps are excluded. Canes, crutches, walkers and folding manual wheelchairs and blood glucose monitors are included but only if they meet six specific conditions: (i) required to ambulate or a blood glucose monitor; (ii) furnished in the "same building" as the underlying course of treatment; (iii) furnished personally by the referring physician, another physician in the group practice (member or independent contractor) or an employee of the referring physician or group practice; (iv) the furnishing physician or group practice meets all the DME supplier standards in Section 424.57(c) of the regulations; (v) the arrangement complies with the Anti-kickback Statute and other applicable law; and (vi) all other requirements of the in-office ancillary services exception are met. The specificity aimed at DME may reflect the governments focus on the abuses of that industry. HCFA deleted the requirement in the Proposed Regulations that physicians not mark-up these items when provided in-office to their patients. HCFA's main concern in expanding the exception for certain DME was to address circumstances where patients needed the DME to ambulate from the physician's office since that need is objectively verifiable.²¹²

4.1. Hospital Services Excluded. HCFA noted that "DHS provided under arrangements with a hospital are inpatient or outpatient hospital services" and are not covered under the in-office ancillary services exception.²¹³

5. Solo Practitioners

5.1. In the preamble, in the course of summarizing basic Stark Law principles of physician compensation, HCFA noted that "the statute implicitly recognizes that solo practitioners will keep all the profits from DHS that fit in the in-office ancillary services

²¹¹ 66 Fed. Reg. at 893.

²¹² 66 Fed. Reg. at 883.

²¹³ 66 Fed. Reg. at 894.

exception, whether performed personally or by others."²¹⁴ HCFA also noted that it expects that in the vast majority of situations a solo practitioner providing DHS for his or her own patients in the physician's own office will not violate the Stark Law either because (i) there would be no "referral" as defined in the Phase I Final Regulations if the services are personally performed, or (ii) if the services are performed by an employee, the physician may be able to meet the in-office ancillary services exception.²¹⁵

5.2. Solo practitioners must follow the same building location requirement to take advantage of the in-office ancillary services exception. The centralized building option is still only available to group practices.²¹⁶

5.3. HCFA also noted that the Stark Law "contemplates that physicians--whether group practice members, independent contractors, or employees--can be paid in a manner that directly correlates to their own personal labor, including labor in the provision of DHS. In other words, "productivity," as used in the statute, refers to the quantity and intensity of a physician's own work, but does not include the physician's fruitfulness in generating DHS performed by others (that is, the fruits of passive activity)."²¹⁷

5.4. HCFA expressly refused to consider "incident to" services as part of productivity outside of a bona fide group practice. HCFA also noted that, "[i]n the case of independent contractors under the personal service arrangements exception and employees under the bona fide employment exception, the amount of compensation for personal productivity is limited to fair market value for the services they personally perform. The fair market value standard in these exceptions acts as an additional check against inappropriate financial incentives." In addition, the personal service arrangements exception and several other exceptions include restrictions on compensation that vary based on the volume or value of referrals.²¹⁸

6. Additional Exception

HCFA specifically requested comments on whether a limited additional exception is warranted for referrals to a physician's spouse in certain circumstances, "particularly in underserved areas, where a spouse may be the *only* qualified provider of a particular DHS."²¹⁹

I. OTHER EXCEPTIONS RELATED TO BOTH OWNERSHIP/INVESTMENT AND CONTRACTORS.

1. Services Furnished to Enrollees of Certain Prepaid Health Plans

The exception for services furnished by an organization (or its contractors or subcontractors) to enrollees of a prepaid health plan provided in the Phase I Final Regulations is

²¹⁴ 66 Fed. Reg. at 876.

²¹⁵ 66 Fed. Reg. at 891.

²¹⁶ 66 Fed. Reg. at 888.

²¹⁷ 66 Fed. Reg. at 876.

²¹⁸ 66 Fed. Reg. at 876.

²¹⁹ 66 Fed. Reg. at 885.

substantially identical to the Proposed Regulation, except that the exception has been modified to include services provided to enrollees of a coordinated care plan as defined in Section 1851(a)(2)(A) of the Act. The exception protects any referrals by physicians for DHS to a managed care organization that has a Medicare managed care contract.²²⁰ Additionally, the text of the Phase I Final Regulations has been amended to clarify that downstream providers (*i.e.*, contractors or subcontractors of a prepaid health plan) are also protected under the exception.

The exception applies to services furnished²²¹ by an organization (or its contractors or subcontractors) to enrollees of one of the following types of prepaid health plans: (i) an HMO or a CMP in accordance with a contract with HCFA under Section 1876 of the Act and 42 C.F.R. Part 417; (ii) a health care prepayment plan in accordance with an agreement with HCFA under Section 1833(a)(1)(A) of the Act and 42 C.F.R. Part 417; (iii) an organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under Section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under Section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note); (iv) a qualified HMO (within the meaning of Section 1310(d) of the Public Health Service Act); and (v) a coordinated care plan (within the meaning of Section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under Section 1857 of the Act and 42 C.F.R. part 422.²²²

It is important to note that the exception is not applicable to services provided to enrollees in any other plan or line of business offered or administered by the same organization (*i.e.*, services provided to non-enrollees of a protected prepaid plan). Further, the exception does not apply to various Medicaid arrangements, including Medicaid managed care plans. The preamble to the Phase I Final Regulations states that Medicaid managed care will be addressed in Phase II of the rulemaking.²²³

2. Clinical Laboratory Services Included in Global Rate

The exception is the same as it appeared in the Proposed Regulation. The exception applies to clinical laboratory services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice, if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.²²⁴ Any such services will not be deemed to be DHS for purposes of the Stark Law.

3. Academic Medical Centers

HCFA has recognized that faculty practice plans are typically involved in complex organizational arrangements that do not fit comfortably or at all in existing exceptions. In response, the Phase I Final Regulations include a new exception for services provided by an

²²⁰ 66 Fed. Reg. at 911.

²²¹ See Section E.2 for a discussion of the definition of "entity" which clarifies that that a person or entity is considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient's behalf. The revised definition of entity will permit physician ownership of network-type HMOs, MCOs, PSOs and IPAs.

²²² 42 C.F.R. §411.355(c).

²²³ 66 Fed. Reg. at 912.

²²⁴ 42 C.F.R. §411.355(d).

academic medical center that takes into account the unique circumstances of a faculty practice, including the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings.²²⁵ Under this exception, the Stark Law referral prohibition will not apply to services provided by an academic medical center if the arrangement meets all of the following four requirements:

- (i) The referring physician must be a bona fide employee of a component²²⁶ of an academic medical center on a full-time or substantial part-time basis, licensed to practice medicine in the state, holding a bona fide faculty appointment at the affiliated medical school and providing either substantial academic or substantial clinical teaching services for which he or she is paid as an employee of the academic medical center.²²⁷
- (ii) The total compensation paid for the prior 12 month period (or fiscal year or calendar year) from all components of the academic medical center to the referring physician must be set in advance and, in the aggregate, can not exceed the fair market value of the services provided and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by that physician within the academic medical center.²²⁸
- (iii) The academic medical center itself meets the following three conditions: (a) all transfers of money between its components directly or indirectly supports the missions of teaching, indigent care, research or community service; (b) the relationship of the components is set forth in a written agreement adopted by the governing body of each component; and (c) all money paid to a referring physician for research is used solely for the support of bona fide research.²²⁹
- (iv) The referring physician's compensation arrangement can not violate the Anti-kickback Statute.²³⁰

An "academic medical center" for purposes of the exception shall consist of all of the following: (i) an accredited medical school (including a university, when appropriate); (ii) an affiliated faculty practice plan that is a nonprofit, tax-exempt organization under Section 501(c)(3) or (c)(4) of the Internal Revenue Code (or is a part of such an organization under an umbrella designation); and (iii) one or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members, and where a majority of

²²⁵ 66 Fed. Reg. at 916. This exception is in addition to other exceptions that may apply in particular circumstances; an arrangement need only fit within one available exception.

²²⁶ A "component" of an academic medical center means "an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation." 42 C.F.R. §411.355(e)(1). For purposes of the exception, an academic medical center may have some, but need not have all, of these components. The minimum requirements to fit within the exception are a medical school, a faculty practice plan, and a hospital. 66 Fed. Reg. at 916.

²²⁷ 42 C.F.R. §411.355(e)(1)(i).

²²⁸ 42 C.F.R. §411.355(e)(1)(ii).

²²⁹ 42 C.F.R. §411.355(e)(1)(iii).

²³⁰ 42 C.F.R. §411.355(e)(1)(iv).

all hospital admissions are made by physicians who are faculty members.²³¹ The preamble to the Phase I Final Regulations notes that the last proviso ensures that the exception only protects physician compensation in genuine academic medical settings.²³²

The purpose of the bona fide employee condition is to ensure that protected physicians are truly engaged in an academic medical practice. The exception does not protect payments to physicians who provide only occasional academic or clinical teaching services or who are principally community practitioners.²³³ As with corresponding provisions in other exceptions, any remuneration paid to physicians must be for bona fide services provided by the physicians and not for referrals. The preamble notes that the fair market value of services in an academic medical practice should be comparable to the aggregate compensation paid to physicians practicing in similar academic settings located in similar environments.²³⁴ Moreover, the regulation is not intended to preclude productivity bonuses paid to academic medical center physicians on the basis of services they personally perform.²³⁵ It is important to emphasize that all compensation from all components of the academic medical center paid to the referring physician must be set in advance.²³⁶ In practice, it is likely that this requirement will serve to limit the application of the exception. Many traditional faculty practice plans base compensation in whole or in part on a percentage of professional fees generated or collected. Moreover, because the compensation paid to academics generally flows from a number of sources, it will be difficult in many instances to set the referring physician's total compensation for the year in advance.

The conditions imposed on the academic medical center in 42 C.F.R. § 411.355(e)(3) are to ensure that (i) the academic medical center is bona fide and that transfers of funds are not inappropriate payments of indirect compensation for referrals and (ii) that all money paid to a referring physician for research is used solely to support bona fide research and is not a disguise for additional payments for referrals.²³⁷

4. Implants in an ASC

HCFA has created a new exception for implants including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices and implanted DME furnished in a Medicare-certified ASC under the following conditions: (i) the implant is furnished by the referring physician or a member of the referring physician's group practice in an ASC with which the referring physician has a financial relationship; (ii) the implant is implanted in the patient during a surgical procedure performed in the same ASC

²³¹ 42 C.F.R. §411.355(e)(2).

²³² 66 Fed. Reg. at 916.

²³³ 66 Fed. Reg. at 916.

²³⁴ 66 Fed. Reg. at 916. Relevant factors in determining a similar academic setting include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace.

²³⁵ 66 Fed. Reg. at 916.

²³⁶ See Section E.6.4. of this Article for a discussion of the meaning of "set in advance." As noted therein, compensation arrangements that are based in whole or in part on a percentage of revenues or collections will not be considered to be set in advance.

²³⁷ 66 Fed. Reg. at 916-917.

where the implant is furnished; (iii) the arrangement for the furnishing of the implant does not violate the Anti-kickback Statute; and (iv) all billing and claims submission for the implants complies with all Federal and State laws and regulations.²³⁸

In the preamble to the Phase I Final Regulations, HCFA noted that implanted prosthetics, implanted prosthetic devices and implanted DME are not included in the bundled ASC payment rate and thus would otherwise be treated as DHS when implanted in an ASC.²³⁹ HCFA recognized that without the benefit of this exception, it is likely that these procedures would be moved to more costly hospital outpatient settings. Further, the exception is consistent with Congress's decision not to include ambulatory surgical services as DHS.

The exception is limited in that it is not applicable to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to and implanted in the patient. The preamble specifically states that the exception does not protect arrangements between physicians and manufacturers or distributors of implants in cases where the manufacturer or distributor furnish DHS through subsidiaries and affiliates.²⁴⁰ Further, the exception does not protect items implanted in settings other than an ASC although other exceptions may be applicable in such circumstances (*e.g.*, the in-office ancillary services exception may protect implants provided within the physicians own practice).²⁴¹

5. Dialysis Related Outpatient Prescription Drugs

In recognition that Congress did not intend the Stark Law to preclude physician ownership of ESRD facilities, HCFA has created a new exception for EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility owned by physicians.²⁴² The exception is applicable under the following conditions: (i) the EPO and other dialysis-related drugs are furnished in or by an ESRD facility; (ii) the arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the Anti-kickback Statute; and (iii) the billing and claims submission for the EPO and other dialysis-related drugs complies with all Federal and State laws and regulations.²⁴³

For purposes of the exception, "furnished" means that the EPO or drugs are either administered or dispensed to a patient in or by the ESRD facility, even if the EPO or drugs are furnished to the patient at home. "Dialysis-related drugs" means certain drugs required for the efficacy of dialysis, as identified on the HCFA web site and in annual updates published in the Federal Register.²⁴⁴ The exception is limited in that it does not apply to any financial relationships between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.²⁴⁵

²³⁸ 42 C.F.R. §411.355(f).

²³⁹ 66 Fed. Reg. at 934.

²⁴⁰ 66 Fed. Reg. at 934.

²⁴¹ 66 Fed. Reg. at 934.

²⁴² 66 Fed. Reg. at 938.

²⁴³ 42 C.F.R. §411.355(g).

²⁴⁴ As noted above, the HCFA website address is <http://www.hcfa.gov>.

²⁴⁵ 42 C.F.R. §411.355(g)(4).

6. Preventive Medicine

HCFA has created a new exception for certain preventive screening tests, immunizations, and vaccines that meet the following conditions: (i) the preventive screening tests, immunizations, and vaccines are subject to HCFA-mandated frequency limits; (ii) the preventive screening tests, immunizations, and vaccines are reimbursed by Medicare based on a fee schedule; (iii) the arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the Anti-kickback Statute; and (iv) the billing and claims submission for the preventive screening tests, immunizations, and vaccines complies with all Federal and State laws and regulations.²⁴⁶ In order to qualify under this exception, the preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be identified by the CPT and HCPCS codes included on the HCFA web site and in annual updates published in the Federal Register.

7. Eyeglasses and Contact Lenses

In recognition that Medicare reimbursement for eyeglasses and contact lenses is limited and presents little opportunity or incentive for overutilization, HCFA has excluded referrals for eyeglasses and contact lenses from the reach of the Stark Law.²⁴⁷ The Phase I Final Regulations include a new exception for eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery under the following conditions: (i) the eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in 42 C.F.R. §410.36(a)(2)(ii) and §414.228, respectively; (ii) the arrangement for the furnishing of the eyeglasses or contact lenses does not violate the Anti-kickback Statute; and (iii) the billing and claims submission for the eyeglasses or contact lenses complies with all Federal and State laws and regulations.²⁴⁸

J. NEW COMPENSATION ARRANGEMENT EXCEPTIONS²⁴⁹

1. Fair Market Value Exception (the "FMV Exception")

The FMV Exception set forth in the Proposed Regulations has been adopted with a few revisions and applies to compensation resulting from a commercially reasonable arrangement between an entity and a physician or physician group.²⁵⁰ This exception is available for compensation arrangements between an entity and either a physician (or immediate family member) or any group of physicians (even if the group does not meet the definition of a group practice), for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, if the arrangement is set forth in an agreement that meets the following conditions: (i) it is in writing and signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement; (ii) it specifies the time frame for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course

²⁴⁶ 42 C.F.R. §411.355(h).

²⁴⁷ 66 Fed. Reg. at 936.

²⁴⁸ 42 C.F.R. §411.355(i).

²⁴⁹ 42 C.F.R. §411.357.

²⁵⁰ 66 Fed. Reg. at 918.

of a year (however an arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change); (iii) it specifies the compensation that will be provided under the arrangement; (iv) the compensation is set in advance, is consistent with FMV and is not determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician; (v) it involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; (vi) the arrangement complies with a Anti-kickback Statute safe harbor, has been approved by the OIG pursuant to the issuance of a favorable advisory opinion²⁵¹, or does not violate the Anti-kickback Statute²⁵²; and (vii) the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a state or federal law.²⁵³

A notable change to the Phase I Final Regulations is that the Proposed Regulation would have protected compensation arrangements in which, among other things, the methodology for determining the compensation was set in advance. The Phase I Final Regulations require that the actual compensation must be set in advance.²⁵⁴ Other notable changes to the Phase I Final Regulations are the elimination of the requirement that the written document cross-reference other agreements between the parties, a change in the requirement that the arrangement comply with the Anti-kickback Statute to requiring that the arrangement not violate the statute, and the addition of a provision to mirror Section 1877(e)(3)(A)(vi) of the Act (which provides the statutory exception for personal service arrangements) which clarifies that the services performed under the agreement cannot involve the counseling or promotion of a business arrangement or other activity that violates Federal or State law.²⁵⁵ With respect to the "improper counseling or promotion" requirement, the commentary to the Phase I Final Regulations states that HCFA "believe[s] that this condition is implied throughout the statute."²⁵⁶ Thus, it appears that HCFA intends to disqualify any arrangement held to involve any such improper counseling or promotion from protection under the Stark Law.

A particular concern regarding the application of this exception to physician recruitment arrangements is HCFA's explicit recognition that many recruitment arrangements offer "extra" payments to induce physicians to relocate and thus will not be covered by the exception because the compensation provided the physician will be in excess of the FMV of the services provided.²⁵⁷ HCFA, however, does recognize that physician recruitment arrangements may be covered by the FMV exception or the physician recruitment exception²⁵⁸ depending on the specifics of the arrangement. Moreover, HCFA states in the commentary to the Phase I Final

²⁵¹ The preamble to the Phase I Final Regulations makes it clear that only the requestor of the opinion will be able to rely on an advisory opinion to meet this criteria.

²⁵² The requirement that the arrangement not violate the Anti-kickback Statute is explicitly included in most of the new exceptions set forth by HCFA in the Phase I Final Regulations. Section 1877 (b) (4) of the Act permits HCFA to except from the Stark Law financial arrangements that do not pose a risk of program or patient abuse. The anti-kickback proviso of the new exceptions is derived from that statutory requirement.

²⁵³ 42 C.F.R. §411.375(l).

²⁵⁴ See discussion of "set in advance" in Section E.6.4 of this article.

²⁵⁵ 66 Fed. Reg. at 917-918.

²⁵⁶ 66 Fed. Reg. at 918.

²⁵⁷ 66 Fed. Reg. at 918.

²⁵⁸ See 42 §411.357(h).

Regulations that it will consider comments on recruitment arrangements in Phase II of the rulemaking.²⁵⁹

2. Non-Monetary Compensation up to \$300

The Proposed Regulation included an exception for "de minimis compensation" in recognition of the fact that physicians and their immediate family members are often given non-cash items or services that have a relatively low value and are not part of a formal, written agreement, on the basis that such compensation is unlikely to cause overutilization, if held within reasonable limits. The Phase I Final Regulations adopt the Proposed Regulation with a few changes.²⁶⁰ The exception applies to compensation from an entity in the form of items or services (excluding cash or cash equivalents) that does not exceed an aggregate of \$300 per year, if the following conditions are satisfied: (i) the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician; (ii) the compensation may not be solicited by the physician or the physician's practice; and (iii) the arrangement does not violate the Anti-kickback Statute.²⁶¹

The most noteworthy change from the Proposed Regulation is the elimination of the "similarly situated" standard which would have required that the entity providing the compensation make it available to all similarly situated individuals. This standard was designed to ensure that protected compensation was not paid primarily to reward high referrers. In order to ensure the same end, the Phase I Final Regulations augment the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated between the parties.²⁶² Another change from the Proposed Regulation was the inclusion of the "no-solicitation" provision which means the gift from the entity to the physician must be a gift in the ordinary meaning of the term (*i.e.*, a voluntary transfer) and excludes from protection any compensation solicited by a physician or his practice (presumably this means that although a hospital may provide donuts in its physician lounge, a physician may not make a request that the hospital provide jelly donuts as opposed to sugar donuts).

3. Incidental Medical Staff Benefits

The Phase I Final Regulations add a new exception for incidental benefits given to a hospital's medical staff members.²⁶³ The new exception is in response to HCFA's recognition that many of the incidental benefits that hospitals provide to medical staff members do not qualify for protection under the employment exception because most members of a hospital's medical staff are not hospital employees, and, further, do not qualify for protection under the FMV Exception because, to the extent that the medical staff membership is the only relationship between the hospital and certain physicians, there is no written agreement between the parties to which these incidental benefits could be added.²⁶⁴

²⁵⁹ 66 Fed. Reg. at 919.

²⁶⁰ 66 Fed. Reg. at 920.

²⁶¹ 42 C.F.R. §411.357 (k).

²⁶² 66 Fed. Reg at 920.

²⁶³ 42 C.F.R. §411.357(m).

²⁶⁴ 66 Fed. Reg at 920-922.

The exception provides that medical staff incidental benefits are excepted from Section 1877 of the Act, if the benefits in question are: (i) offered by a hospital to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties; (ii) offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital and its patients; (iii) provided by the hospital and used by the medical staff members only on the hospital's campus; (iv) reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital; (v) consistent with the types of benefits offered to medical staff members by other hospitals within the same local region or, if no such hospitals exist, by comparable hospitals located in comparable regions; (vi) of low value (*i.e.*, less than \$25) with respect to each occurrence of the benefit; (vii) not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; and (viii) not violative of the Anti-kickback Statute.²⁶⁵

In the commentary to the Phase I Final Regulations, HCFA cautions that medical staff incidental benefits should be reviewed to ensure compliance with other applicable laws and regulations including the Anti-kickback Statute.²⁶⁶ The commentary goes on to state that medical staff incidental benefits that do not meet the conditions of the exception could constitute prohibited remuneration and, therefore, would be permitted under the Stark Law only if an exception applies. Listed as examples of the types of benefits that would not be protected are the provision of malpractice insurance by a hospital only to its emergency room physicians (these benefits are not protected because they are not offered to all members of the hospital's staff) or the provision of medical transcription services (these benefits are not protected because the value of the benefit would be more than incidental).²⁶⁷ The commentary further notes that an exception for professional courtesy could be developed and the issue will be addressed in Phase II of the rulemaking.²⁶⁸

4. Risk Sharing Arrangements

In recognition that a typical risk-sharing arrangement between a physician and a managed care plan (*e.g.*, capitation or withhold arrangement) would not be eligible for the statutory exceptions for bona fide employment relationships or personal service arrangements, the Phase I Final Regulations include a new compensation exception for bona fide risk-sharing arrangements between a managed care organization and a physician for services provided to enrollees of a health plan.²⁶⁹ This exception applies to compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Anti-kickback Statute or any law or regulation

²⁶⁵ 42 C.F.R. §411.357(m).

²⁶⁶ 66 Fed. Reg. at 921.

²⁶⁷ 66 Fed. Reg. at 920-922.

²⁶⁸ 66 Fed. Reg. at 922.

²⁶⁹ For purposes of this exception, "health plan" and "enrollees" have the meanings ascribed to those terms in 42 C.F.R. §1001.952(l).

governing billing or claims submission.²⁷⁰ In practice, this exception should protect compensation arrangements between physicians and most employer-sponsored and commercial managed care plans.

5. Compliance Training

The Phase I Final Regulations include a new compensation exception for compliance training provided by a hospital to a physician (or the physician's immediate family member) who practices in the hospital's local community or service area, provided the training is held in the local community or service area. For purposes of the exception, "compliance training" means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).²⁷¹

6. Home Health Plan of Care

In the Phase I Final Regulations, HCFA has liberalized the rules regarding financial relationships between physicians and home health agencies and has reconciled the Stark Law with the physician certification requirements for home health services contained in 42 C.F.R. § 424.22(d). Although the effective date of the Phase I Final Regulations is January 4, 2002, the revisions to 42 C.F.R. § 424.22(d) were originally scheduled to become effective February 5, 2001.²⁷²

²⁷⁰ 42 C.F.R. §411.357(n)

²⁷¹ 42 C.F.R. §411.357(o)

²⁷² On January 20, 2001 the Bush administration implemented a 60-day delay on all regulations promulgated during the Clinton administration that had not yet taken effect as of January 20, 2001. Thus, the effective date of the revisions to 42 C.F.R. §424.22(d) is now April 6, 2001. See 66 Fed. Reg. 8771 (February 2, 2001).