Holland+Knight

Stark Handbook

(Phase I and Phase II)

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120 Days and Counting

CMS finally issued its "Phase II" Stark Regulations March 26, 2004. The Regulations are effective in 120 days, or on July 24, 2004. CMS provides a 90 day comment period, so there are apt to be further tweaks, but, for the most part, "this is it."

While the Phase II Regulations go a long way to clarifying what Stark is all about, and while the Regulations also provide important liberalization, the Regulations *do not* contain any "grandfather" provisions.

That means that existing financial arrangements between physicians and practices, hospitals, surgery centers, lessors, suppliers and others in the health care industry must be reviewed, and when not compliant, changed. And physicians and their advisors have 120 days to accomplish that.

What happens when a physician or other health care provider does not comply with Stark? We touch on the penalties in our introduction. Suffice to say, it is illegal for a physician or other health care provider to bill Medicare if the physician is not "Stark-compliant." If Medicare is billed, and refunds aren't made, the physician risks prosecution for false claims, loss of license, fines and penalties.

Furthermore, Phase II Regulations have added a reporting requirement and provided that failure to report when requested can result in a fine of up to $10,000 a day. Hiding noncompliance has become more difficult and costly.

So compliance is important.

At various places in our Handbook, we provide "Practice Alerts" to point out issues we think require immediate attention during the 120 day phase-in period.

For example:

- Physicians and practices with hospital recruiting agreements will have to bring them into swift compliance.
- Physicians being compensated under medical director agreements will want to re-compute compensation for "fair market value" compliance under the new hourly rate safe harbors.
- Cardiologists contemplating purchasing nuclear medical equipment (currently nuclear medicine is not considered a Stark "designated health service") may want to be sure they have options to dispose of the equipment if the rules change (Phase II points out the nuclear exception is under further study by CMS).
- Husband and wife physicians who are in different practices will want to see if they can refer to each other under the new narrow — very narrow — rural husband and wife referral exception.

- Group practices will want to determine if their "percentage compensation" arrangements with their physicians fall within the revised definition of "set in advance."
- Practices selling equity ownership interests in the practice to physicians will want to determine if their arrangements fit into the newly-defined "isolated transactions" exception, which now permits installment sales.

So there is a lot of work that must be accomplished in the next 120 days.

Hopefully, this guide will highlight the Stark requirements important to your practice or company. However, Stark is complex and the Phase I and Phase II Regulations and Commentary are lengthy. The risks of violation are substantial.

This guide is not intended to be complete, or to substitute for a carefully study of the Regulations. Be sure you seek advice on the issues that are important to you and your company or practice.

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[A] Introduction

The present version of Section 1877 of the Social Security Act, the federal physician self-referral law[2], known as "Stark II," (referred to herein as "Stark" or the "Stark Statute") became effective January 1, 1995. Although the statute was intended to provide a "bright line" of do's and don'ts for physicians it has proven to be anything but bright or clear.

Proposed regulations were issued in 1998.[3] Final "Phase I" regulations were published January 4, 2001, with a deferred effective date of January 4, 2002.[4]

Final "Phase II" Regulations were published March 26, 2004.[5] The Phase II Regulations are substantially different from the 1998 Proposed Regulations. Phase II Regulations replace the 1998 Proposed Regulations, modify the Phase I Regulations and fill in gaps not covered by the Phase I Regulations. The Phase II Regulations leave to future rule-making the effect of Stark on Medicaid. The Phase II Regulations are effective 120 days after publication (that date should be July 24, 2004), and also provide a 90-day comment period. The March 26, 2004 Regulations are identified by CMS as the "interim final rule." Thus, further changes in the Phase II Regulations are likely.

Compliance with Stark, however, is mandatory for physicians who participate in the Medicare system. There is no avoiding the effect of Stark.

> ***Practice Alert****: Physicians and advisors will logically ask: What is the effect of Stark on existing agreements? The Regulations provide no grandfather provision for existing agreements; thus, existing agreements must be brought into compliance by July 24, 2004. If they are not, the practitioners will be in violation of Stark.*

Unlike the Medicare Anti-Kickback Statute, which is a criminal statute requiring at least some determination of criminal intent, the Stark Statute is a civil statute requiring strict compliance. Intent to violate or substantial compliance with the Stark Statute has no bearing on whether an activity is or is not legal. Violation, no matter how unintentional or technical, is sufficient to invoke the Stark Statute.

The Stark Statute provides severe civil sanctions, including denial of reimbursement and a civil monetary penalty of up to $15,000 for each bill or claim for a service known (or which should have been known) to be improper. A civil penalty of up to $100,000 can also be imposed for each arrangement or scheme that a physician or health care entity knows or should have known has a principal purpose of assuring prohibited referrals.[6]

> ***Practice Alert.*** *The Phase II Regulations recognize that a practice could become noncompliant with Stark unintentionally. CMS recognized that under such circumstances, the practice should not be penalized. Thus, a new §411.353(f) has been added to the Regulations. Essentially, if the DHS entity has been in strict compliance with Stark for not less than 180 consecutive days and then falls out of compliance through no fault of its own, the DHS entity will have 90 days to return to compliance. This new rule cannot be used more than once in a three-year period. The example given is a practice located in a rural area operating under the liberal rural area rules is reclassified as non-rural because of population shifts.*[7] *This rule will not be of help for a practice that is not in compliance when the Phase II Regulations become effective.*

Stark II broadened the coverage of the original Stark Law from clinical laboratories to an expansive list of "designated health services." Stark I, which dealt only with referrals to clinical laboratories, was effective January 1, 1992. The 1998 Proposed Stark Regulations, issued in January 1998,[8] are now considered revoked.

Congress has received severe criticism of the Stark Statute and from time to time changes have been under consideration. In the meantime, this very complex and vague legislation affects every practice, from recruiting to operations, physician compensation, promotion, acquisition, merger or disposition.

The American Health Lawyers Association held a Public Interest Colloquium in January, 1999 titled *Fraud and Abuse: Do Current Laws Protect the Public Interest?*[9] The report concludes: "Panelists agreed that 'something has to be done about Stark.'"

Apparently, however, the criticism has not deterred the U.S. Attorney. James Sheehan, Assistant U.S. Attorney in Philadelphia, spoke to the Health Care Compliance Association on June 15, 1999, and identified several areas where violations of Stark, though a civil statute, could be considered as part of a criminal fraud case.[10] Unofficially, despite the vagaries and lack of regulations, it was reported in early 2001 that at least 50 Stark investigations by the Justice Department were underway.

Thus, until the law is changed, the broad reach of the Stark Statute will remain. Physicians as well as their advisors must consider the reach of Stark when designing or evaluating compensation arrangements, leases, ancillary service agreements, hospital relationships, recruiting arrangements, entertainment expenses, as well as sales or purchases of medical equipment, facilities and practices.

> ***Practice Alert.*** *The complexities of Stark may cause physicians and their advisors to lose sight of the fact that, Stark-compliant transactions must meet the separate requirements of the Anti-Kickback Statute and the various state laws. State laws, the Anti-*

Kickback Statute and the Stark Statute are mutually exclusive; therefore fitting a transaction under one statute does not mean that the transaction meets the requirements of the other statutes. At times, the statutes appear in conflict, making any decisional process hazardous.

As an example of conflicting state law, the Medical Board in Florida has ruled that Florida physicians' compensation is limited to compensation for the physician's services and his or her "incident to" services and cannot be based upon ancillary service revenues, which include Stark-defined "designated health services". Thus, Florida physicians face state-mandated requirements that are stricter than the Stark requirements.

An argument has been made that the Safe Harbor Regulations promulgated under the Anti-Kickback Statute provide exceptions to the Stark Statute by application of the "permissible exceptions" provision of Stark. [11] Permissible exceptions under Stark include "any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." [12] The argument is that a transaction that is compliant with the Safe Harbor Regulations under the Anti-Kickback Statute should be "Stark safe."

However, in its 1999 Commentary to the Final Safe Harbor Regulations, the OIG makes it clear that the Anti-Kickback Statute and the Stark Statute are separate and distinct laws[13] The OIG's position is reiterated by CMS in the Phase I Regulations.[14]

In some cases, the criteria for Stark exceptions overlap the Anti-Kickback Statute Safe Harbors (*i.e.,* the space rental and leasing exceptions) and in other cases the criteria, even for the same subject matter, are entirely different (i.e., hospital recruiting agreements).

The Stark Statute contains several statutory exceptions designed to permit physicians to maintain a relationship with a DHS entity under described circumstances. Some of these exemptions apply solely to ownership arrangements; others apply solely to compensation arrangements; and still others apply to both ownership and compensation arrangements. The Legislation grants the Secretary of the HHS the power to promulgate additional exceptions for financial relationships that in the opinion of the Secretary do not pose a risk to the Medicare program.

[B] The Stark Statute: Prohibition on Physician Referrals

The Stark Statute provides, with certain exceptions which we will discuss, that if a physician (or an immediate family member of the physician) has a financial relationship with an entity, then:

1. The physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under Medicare or Medicaid; and

2. The entity may not present or cause to be presented a claim under Medicare or Medicaid or a bill to any individual, third party payer or other entity for designated health services furnished pursuant to a referral prohibited under the above paragraph 1.[15]

The Commentary to the 1998 Proposed Stark Regulations provided:

> First, we are taking the position that the statute does not affect a physician's compensation for services other than designated health services. Thus…a group can distribute profits from services other than designated health services in any way it sees fit. For example, a group can distribute profits from the physicians' own designated health services under an even split, based on referrals, or according to the amount of a physician's investment in the group, seniority, [and] hours spent…. The practice can also offer different types of sharing of profits or other kinds of compensation arrangements…to different physicians or groups of physicians. [16]

The Phase I Regulations adopt that same position,[17] and put forth a two-pronged test:

> In general, we believe that a sensible approach is to ask two questions: (1) Is there a direct or indirect financial relationship between the referring physician and the entity furnishing DHS [designated health services]? (2) Is there a referral for DHS from the physician to the entity? If the answer to both questions is in the affirmative, section 1877 of the Act [the Stark Statute] is violated unless an exception applies.[18]

The Phase II Stark Regulations summarize the effect of the Stark Law and the Phase I and Phase II Regulations:

> Most physician ownership in DHS entities is prohibited. Most physician compensation must be fair market value…The basic sanction under section 1877 of the [Social Security] Act is nonpayment for DHS referred by a physician with an improper financial relationship with the DHS entity.[19]

The Phase II Regulations, 42 C.F.R. §411.353 (a), clarify:

- Neither the physician nor members of the physician's immediate family with a direct or indirect financial relationship with the entity can make a referral to a DHS entity when payment is made under Medicare.
- The physician's prohibited relationship is not imputed to the physician's group practice or its staff members; however, referrals by the group practice or its staff *may* be imputed to the physician *if* the physician directs or controls the referrals.

The Phase II Regulations, 42 C.F.R. §411.353, provide for two exceptions to the prohibition against its billing for DHS when there is a prohibited relationship:

- A DHS entity may bill and be paid for DHS when it has no knowledge that a physician has a prohibited relationship with it, and
- A DHS entity may bill and be paid for DHS during a temporary period of noncompliance when it meets certain requirements specified in the Regulations.

These exceptions are discussed later in this paper.

[C] Key Stark Definitions

[1] Physician

The Regulations adopt the definition of physician contained in §1861(r) of the Social Security Act.[20] *Physician* includes a doctor of medicine, osteopathy, dental surgery, dental medicine, podiatry, optometry, and chiropractic medicine.

[2] Immediate Family Member

Members of the immediate family of a physician include husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of any grandparent or grandchild.[21]

[3] Financial Relationships (Direct and Indirect Compensation and Ownership)

Under the Stark Statute a *financial relationship* between a physician or an immediate family member and an entity is either (1) an ownership or an investment interest in an entity or (2) a compensation arrangement between an entity and the physician or an immediate family member of the physician.[22]

The ownership interest may be in the form of equity, debt, or any other means and may include an interest in an entity that holds an interest in an entity providing designated health services.

The Regulations define both *direct* and *indirect financial relationships*.[23] Under the Regulations, a *direct financial relationship* is a relationship without intervening entities. An *indirect financial relationship* exists when there are one or more intervening persons or entities in an unbroken chain between the physician (or family member) and the DHS entity.[24]

The Phase II Regulations clarify that a financial relationship exists between the referring physician and the DHS entity even when the financial relationship is wholly unrelated to DHS or meets one of the Stark exceptions.[25]

Examples of financial relations include: A physician's wife working at a non-profit hospital creates a financial relationship between the hospital and the physician. A physician who has financial relationship that involves only private pay patients with an

MRI facility has a financial relationship with the MRI facility for Stark purposes. A physician inventor who is paid royalties from a DME company has an indirect financial relationship with a hospital that purchases the DME equipment when the physician has staff privileges at the hospital, whether or not the physician recommends the equipment. A pathologist employed by a practice that has an exclusive hospital contract has a direct financial arrangement with the hospital.

The Commentary to the Phase I Regulations provides an example of a physician ownership in a physician practice management company (a PPM) as being an indirect financial relationship when the revenues of the management company are determined on a percentage basis, varying with the volume of designated health services provided by the managed physician practice.[26]

The Commentary to the Phase II Regulations provide an example where a practice leasing office space from a hospital (even when the lease falls under the Stark lease exception) creates an indirect financial relationship between the practice physicians and the hospital.[27]

The Regulations provide that an ownership in a parent company is an ownership in its subsidiary; however, an ownership in a subsidiary is not an ownership in the parent.

Secured debt is considered an ownership relationship and unsecured debt is considered a compensation relationship. Contrary to the 1998 Proposed Stark Regulations, an interest in a retirement plan is not considered to be an ownership interest. An ownership interest that meets a Stark "ownership" exception under 42 C.F.R. §§411.355 or .356 need not also meet a Stark "compensation" exception under 42 C.F.R. §411.357.[28]

The Phase I Regulations also added a *knowledge* element to the definition of financial relationship. The element is part of both the indirect compensation and indirect ownership definitions.

Under the knowledge test, for an indirect financial relationship to exist, the DHS entity furnishing the designated health service must have actual knowledge of, or act in a reckless disregard or deliberate ignorance of, the fact that the referring physician or family member has a financial relationship with the entity.[29] When considering whether a DHS entity has knowledge, it is not required to know the precise terms or composition of the relationship.[30]

The Regulations also add a permitted exception, 42 C.F.R. §411.357(p), for *indirect compensation* arrangements between the physician and the DHS entity that meet certain criteria.

Essentially, an *indirect compensation arrangement* exists between the physician and the DHS entity when (i) an unbroken chain of entities link the DHS entity and the physician, (ii) the "aggregate" compensation paid to the referring physician varies with, or takes into account, the volume or value of DHS referrals *or* other business generated for the DHS

entity, and (iii) there is knowledge within the DHS entity of the physician's relationship with that entity. For purposes of determining the presence of an indirect compensation arrangement, "percentage," "per click" and "per time" forms of compensation are considered to vary with the volume or value of referrals for the "gross" compensation test.[31]

The *indirect compensation exception* (discussed again under the regulatory exceptions portion of this paper) provided in 42 C.F.R. §411.357(p) provides that an indirect compensation arrangement is excepted from Stark when the arrangement (i) is fair market value and does not take into consideration the volume or value of referrals *or* other business generated by the physician or family member, (ii) is in writing and describes all of the services (however, employment arrangements need not be in writing, but must be for identifiable services and commercially reasonable, even without referrals) and (iii) does not violate the Anti-kickback Statute or other federal or state law governing billings and claims.

For purposes of the indirect compensation exception, "per click," and "per time" compensation arrangements meeting the tests provided in 42 C.F.R. §§411.354(d) (2) and (3) are not deemed to vary with the volume or value of referrals. Percentage compensation, may apply only to personal services; however, a royalty example, provided later in this paper, indicates the percentage arrangement may be broader than personal services.

Under the Phase II Regulations, a physician and the physician's practice entity are considered one. Thus, when the practice has an agreement with the hospital, the physician is deemed to have an agreement with the hospital. Under the Phase I Regulations, under those circumstances, the physician would have been deemed to have an indirect compensation arrangement with the hospital; under Phase II, the arrangement is deemed to be direct, and the physician's compensation from the physician's practice entity would be governed by the direct, not the indirect, compensation regulations. [32]

The indirect compensation exception does not have to meet the "set-in-advance" requirement, discussed later in this paper. [33]

An indirect investment or ownership interest is not permitted. Such an interest requires that there be an unbroken chain of direct ownership interests (more than one) between the referring physician and the DHS entity and that the DHS entity has "knowledge" of the ownership arrangement, as knowledge is defined above in this section.[34]

Co-owners are not presumed to have an indirect ownership in each other. A co-ownership arrangement does not create an indirect compensation arrangement unless the return to the physician owner varies with the volume or value of referrals.

The Regulations provide a test for determining when the "value or volume" test is met in an indirect compensation arrangement exists when the physician has an ownership or investment interest financial relationship:

> If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician.[35]

As clarification of direct and indirect financial relationships, if a physician has an ownership interest in a DME company that leases DME to a hospital where the physician has privileges, the interest of the physician in a DME company creates an indirect financial relationship with the hospital. The indirect relationship is a compensation arrangement (receipt of lease payments by DME company attributed to the physician). If the DME company owned an interest in the hospital the ownership interest would be an indirect ownership interest by the physician. If the hospital owned an interest in the DME company, the physician would not be considered to have an indirect ownership interest in the hospital, since an interest in the subsidiary is not considered to be an interest in the parent.[36]

The Phase II Commentary provides an example of an imaging leasing company co-owned by a physician and a hospital. If the rental arrangement between the company and the hospital is a "per-click" fair market value rental arrangement, the physician's co-ownership would meet the "indirect compensation arrangement exception." The Phase II Commentary is quick to add that the arrangement could, however, violate the Anti-kickback Statute.[37]

Phase I Regulations indicated that unexercised *stock options* created a compensation arrangement. Phase II Regulations modify that conclusion and provide that unexercised stock options, if paid for, can create an investment interest, and if given as compensation, can create a compensation arrangement. [38]

[4] Entity

The Phase I Regulations define *entity* as a physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, agency, trust, corporation, a partnership, a limited liability company, a foundation, a not-for-profit corporation or an unincorporated association furnishing designated health services, excluding only the physician himself or herself.

An entity is considered as furnishing designated health services if the entity is the person to whom CMS makes payment directly or upon assignment.

However, if there is a reassignment to an employer or other permitted entity, the person receiving the reassignment is the entity, with certain exceptions for MCOs, PSOs, and

IPAs not actually furnishing the service.[39] Manufacturers are not considered entities unless they operate a health care provider, such as a pharmacy.[40]

The Phase II Regulations definition provides that a physician practice, when billing for diagnostic tests (for which there is no markup), is not included within the definition of *entity*. [41]

[5] Referral and Consultation

The Stark Statute definition of *referral* includes a referral for any service provided under Medicare Part B, which includes all physician services.[42] The Phase I Regulations narrow the definition of referral as being either:

1. [T]he request by a physician for, or ordering of, or the certifying or recertifying of the need for, any *designated health service* for which payment may be made under Medicare Part B (or, for purposes of the Medicaid program, a comparable service covered under the Medicaid State plan), including a request for a consultation with another physician and any test or procedure ordered by or performed by (or under the supervision of) that other physician, but not including any designated health service *personally* performed by the referring physician.
2. [A] request by a physician that includes the provision of any other *designated health service* for which payment may be made under Medicare (or, for purposes of the Medicaid program, a comparable service covered under the Medicaid State plan), the establishment of a plan of care by a physician that includes the provision of such a designated health service, but not including any designated health service *personally* performed by referring physician.[43]

The exclusion of services personally performed by a physician from the definition of referral does not extend to services provided by employees, co-workers or independent contractors.[44] Thus, services that can be billed as "incident to" services because they are provided by physician assistants or other staff members under the direction of a physician remain referred services. During Phase I, CMS considered excluding staff work referred by a supervising or group physician from the definition of referrals, but elected to maintain referrals to staff within the definition; thus, these referrals must meet the *in-office ancillary services exception* discussed later.[45]

The exclusion of services personally performed by a physician from the definition of referral applies regardless as to who bills of the services. Thus, personally performed physician services billed by a hospital are excluded; however, the exclusion does not extend to the DHS technical components billed by the hospital.[46]

Phase I Regulations included an exception, 42 C.F.R. §411.353(e), which permits a DHS entity to bill Medicare when the DHS entity is unaware of a prohibited financial relationship between it and the referring physician (this exception, however, would not protect the physician who knowingly makes the referral[47]).

Referrals can be imputed to a physician if the physician controls the referral and the referral is routed or directed through another person, such as the physician's assistant.[48]

The Commentary to the Phase I Regulations address what has become a common occurrence, the referral of a patient from a spouse in one practice to a spouse in another practice. CMS concludes that a referral to a spouse in another practice is not restricted by Stark if the referral is for a physician service unrelated to the furnishing of designate health services. The spouse to whom the referral is made may then, in his or her discretion, provide designated health services, or refer designated health services under the "in-office ancillary services" exception.[49] Phase II Regulations provide a narrow exception for "rural" spousal referrals, which will be discussed later in this paper.

Also excluded under the Stark Statute and the Regulations from the definition of referral is a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic imaging services, and by a radiation oncologist for radiation therapy when the request results from a *consultation* (defined below) initiated by another physician and the test or services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist or a pathologist, radiologist or radiation oncologist in the same group practice.

Phase II modified the definition of *referral* slightly to clarify that the exception for a request by a consulting radiation oncologist includes radiology services and tests that are "ancillary" or "integral" to the radiation oncology services.[50] Thus, an oncologist's request for a related MRI scan is also included in the oncologist's consultation exception.

Phase II Regulations expand the consultation referral exclusion to also include tests or services provided by a pathologist, radiologist, or radiation oncologist in the same group practice.[51]

The Regulations define a *consultation* as (i) the advice of a physician in response to a request by another physician, (ii) when the request and need is documented in the record, (iii) when the consulting physician provides the requesting physician with a written report, and (iv) in respect to radiation oncology providing ongoing services, the oncologist provides periodic reports of the patient's progress to the referring physician.[52]

These consultation exceptions do not cover patients who "self-refer" themselves to a radiation oncologist, pathologist or radiologist; treatment of these patients must be made in accordance with the "in-office ancillary services" exception discussed later. Nor do the consultation exceptions protect the referral to the pathologist, radiologist, or radiation oncologist from another physician.

[6] Designated Health Services

Designated health services includes clinical laboratory services; physical therapy services; occupational therapy services; radiation or other diagnostic services; radiation therapy services; durable medical equipment; parenteral and enteral nutrients, equipment

and supplies; prosthetics, orthotics, and prosthetic devices; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.[53]

The Phase I Regulations provide that designated health services ("DHS") include only DHS billed as such to Medicare. DHS does not include services that are reimbursed as part of a composite rate, such as would be reimbursed for DHS services provided at an ambulatory surgical center.

The Phase I Regulations provide some degree of certainty in the definitions of DHS by defining certain DHS components by CPT/HCPCS Codes. These include clinical laboratory, physical therapy, occupational therapy and speech therapy, radiology and other imaging services, and radiation therapy.[54] Drugs and DME are not defined by CPT/HCPCS codes.

The 1998 Proposed Stark Regulations included nuclear medicine in an expansive definition of *radiology*. The Phase I Regulations exclude nuclear medicine and most invasive radiology procedures from the definition of radiology. Phase II Regulations confirm these exceptions. [55] However, Phase II includes a Commentary that indicates that the exclusion of nuclear medicine may not be final:

> We are continuing to consider the application of section 1877 of the [Social Security] Act to nuclear medicine procedures, but we are not changing the treatment of nuclear medicine procedures under DHS definitions at this time.[56]

> ***Practice Alert.*** *A future change in the exception for nuclear medicine, bringing it back into the definition of radiology, could have a significant economic impact on physicians who purchased ownership interests in expensive nuclear equipment. Radiologists and radiation oncologists may be able to continue to use the equipment under the expanded "consultation" exception, but that exception is not available to nuclear cardiologists. For cardiologists, the use of nuclear equipment would also have to meet the "in-office ancillary services" exception and its "building" tests. These tests would be difficult to meet for free-standing nuclear equipment owned with other physicians...*

Phase II Regulations also modified the definition of *radiology and other imaging services* to clarify that these services exclude from DHS radiology services performed immediately after a procedure to confirm the placement of an item in the procedure.[57]

The Phase II Commentary notes that the definition of *outpatient prescription drugs* will be modified in 2006 when certain prescription drugs become available under recent Medicare revisions. Phase II Commentary also confirms that prescription drugs administered by a physician in the physician's office are in fact "prescription drugs" but

when personally administered by the physician, the administration is not a referral; when administered by staff, the in-office ancillary services exception applies.[58]

Phase II Commentary confirm that lithotripsy is no longer considered DHS; however, contractual arrangements between physicians administering lithotripsy and hospitals where the service is provided are "financial arrangements" for "inpatient or outpatient" hospital services, subject to compliance with the "personal services" exception. [59]

Phase II Regulations and Commentary also provide some clarification for DHS definitions for *clinical laboratory services, physician therapy services, occupational therapy services, durable medical equipment services, parenteral and enteral nutrients, equipment and supplies, prosthetics, orthotics and prosthetic devices and supplies and home health services.*[60]

The Phase I Regulations define *designated health services* as excluding services that are reimbursed by Medicare as part of a composite rate (for example, ASC services (ambulatory surgery center), SNF Part A services (skilled nursing home), and ESRD (end stage renal dialysis facility) composite rate services, except to the extent the specifically enumerated DHS in section 1877(h)(6) of the Social Security Act[61] are themselves payable through a composite rate (thus, home health services and inpatient and outpatient hospital services remain DHS). Phase II Regulations maintain these exceptions. [62]

[7] Physician Services as DHS

The Phase I Regulations provide that the portion of a charge under a CPT/HCPCS Code that is allocated to a physician service is DHS. For example, certain CPT Codes for certain radiology and imaging services include the services of the physician. When so included, the physician's services are considered DHS.[63] The inclusion of the professional services component with the technical component in the definition of DHS radiology and imaging services has been criticized.

Although not changed in the Phase II regulations, the application of the CPT code inclusion is clarified. CMS states in its Phase II Commentary that the inclusion of the radiology and imaging professional component as DHS does not prohibit compensating physicians for these services when personally performed by the referring physician or by another physician within the physician's group practice. Personally performed services are not referred services.

Similarly, services performed under the "physician services" Stark exception can be used to provide these DHS services, and are not limited by the in-office ancillary services exception's building requirements.[64] However, the definition of *physician services* contained in the exception, 42 C.F.R. §411.355(a), specifically excludes "incident to" services that are not physician-performed; thus, if the radiology technical services are performed by the practice's non-physician staff, they do not fall under the physician services exception, and must fall under the *in-office ancillary services* exception.

The basic difference between the two exceptions is that in-office ancillary services must be performed in the same building as other physician services or in a dedicated building. Services under the physician services exception could be performed in the hospital, office or anywhere.

[D] Other Important Stark Definitions and Concepts

[1] Remuneration

Remuneration is broadly defined in Stark.[65] The Phase I Regulations define "remuneration" as any direct or indirect payment or benefit in cash or in kind except:

- The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures or minor billing errors,
- The furnishing of certain items or devices to collect, transport, or store specimens, and
- Certain payments by self-insurers and insurers to physicians for services to covered-plan participants.[66]

The Phase II Regulations broadened the "self-insurer" and "insurer" exceptions slightly to provide that "downstream" payments (payments made by payers to providers for "out of network" services) are included in the exception.[67]

[2] Compensation

Compensation arrangement limitations in Stark apply only to remuneration paid for DHS and do not limit other compensation arrangements.[68]

The Commentary to the Phase I Regulations provides the following discussion about compensation:

> [S]ection 1877 of the Act [the Stark Statute] 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…[But productivity] does not include the physician's fruitfulness in generating DHS performed by others… "Incident to" services are not included in the productivity bonuses under the statute unless the services are incident to services personally performed by a referring physician who is in a *bona fide* group practice."[69]… [P]hysicians wishing to bill DHS "incident to" (and in group practice physicians wishing to obtain productivity bonuses for services incident to their personally performed physician services) must comply with the "incident to" supervision requirements, including the "present and available" requirement…"[70]

The above conclusions are affirmed in the Phase II Regulations.[71]

The Phase I Regulations provide a compensation exception from Stark for *indirect compensation arrangements*. Indirect compensation and the exception are discussed under section [C] [3], Financial Relationships. The application of the indirect compensation definition and the exception, however, is not easy. The physician's ownership and compensation arrangements with his or her group practice must be examined to determine if any compensation from the practice entity is related to the volume or value of DHS referrals to the entity with which the physician has an indirect relationship.

The Phase I Regulations provide that an element in the definition of "indirect compensation" is that the referring physician's compensation from the entity with which the physician has a direct relationship varies with or reflects the volume or value of referrals or other business generated by the referring physician for the entity providing the DHS services.[72] The Phase II Regulations clarify the workings of the exception, discussed in [C] [3] above.

A *Physician incentive plan* means a compensation arrangement between an entity and a physician or a physician group that may directly or indirectly have the effect of reducing or limiting services provided to individuals enrolled with the entity. Generally, the Stark prohibition does not apply to a physician incentive plan that takes into account, directly or indirectly, the volume or value of any referrals or other business generated between the parties if the plan meets the following requirements:

- No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided to a specific individual enrolled with the entity;
- In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary of HHS pursuant to Section 1876(i)(a)(A)(ii) of the Social Security Act, the plan complies with any requirements the Secretary may impose pursuant to such section; and
- Upon request by the Secretary of HHS, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan complies with the requirements of this exception.[73]

The Commentary for the Phase II Regulations clarifies physician compensation issues, differentiating the requirements for group practice physicians from employed or contracted physicians. The Commentary points out that the Stark Statute permits group practices more flexibility than contractor or employee relationships in the way DHS revenues are shared. Outside of the in-office ancillary services context, CMS has attempted to equalize the compensation rights of physicians outside group practice context with the rights of group practice physicians. For example, the "set in advance" requirement for compensation, which applies, for example, to physicians employed at academic centers, is interpreted under Phase II to permit percentage compensation for personal services. The statutory requirement that compensation plans for academic center physicians not consider "other business generated" has been clarified to exclude

personally performed physician services, which are no longer considered a referral.[74] *Set in Advance* is discussed in more detail later in this paper.

CMS Phase II Commentary provides a summarizing chart comparing the statutory and regulatory differentials in DHS compensation between group practice physicians, employed physicians who are not group practice physicians, independent contractor physicians, academic medical center physicians, and physicians employed under the *fair market value* regulatory exception. Of particular note: group practice physicians can be compensated for their own professional services and for "incident to services." Employed physicians who are not group practice physicians, academic center physicians, independent contractor physicians and physicians employed under the fair market value exception cannot be compensated for DHS "incident to" DHS services.[75]

That distinction is an important distinction in any medical practice using physician assistants and other staff personnel to provide patient services.

> ***Practice Alert.*** *Physicians directly employed by hospitals are not group practice physicians because the primary business of the hospital is not the practice of medicine. Therefore, these physicians cannot be compensated on incident to services. If the hospital were to set up a dedicated subsidiary, that subsidiary would qualify as a group practice, permitting the physicians to be compensated on incident to services.*

Phase II Commentary clarifies that, under the "physician services" exception, physicians may be compensated on a flat fee basis for supervision of mid-level employees, provided that the compensation is fair market value. The Phase II Commentary also clarifies that "exclusive contracting arrangements" (such as between a pathologist and a hospital), or compensation based upon quality measures, are permitted when the compensation is fair market value and is not based upon referrals.[76] The Phase II Commentary also confirms that antigens provided by allergists are "physician services."[77]

[3] Employee and Leased Employee

The Stark Statute and the Phase I Regulations define *employee* as a common law employee.[78] A common law employee is determined under the tests provided by the Internal Revenue Code (I.R.C. §3121(d) (2)) and its regulations. The Phase I and Phase II Commentary discussions of group practice requirements provide that group practice "members" are physicians who own or are employed by the group practice. Independent contractors are not group practice members. Leased employees are also not considered group practice members *unless* the leased employees also meet the common law test of employee within the practice. There was some confusion about this in the Phase I Commentary which has been clarified in Phase II. Generally, the issue is one of control and direction.[79]

Practice Alert. *Florida law permits physicians and other licensed professionals to be "leased" to practices from licensed employee leasing companies. When physicians are leased to a practice, to assure their position as "group practice members," their employment arrangements with both the practice and the leasing company must reserve to the practice the important common law control and direction elements.*

[4] Fair Market Value

The Stark Statute defines *fair market value* as the value arrived at by arms-length transactions, consistent with the general market value, and with respect to rentals, the value of the property for general commercial purposes not taking into account its intended use, and with further respect to realty, not taking into consideration the proximity to the lessor when the lessor is a potential source of patient referrals.[80]

The statutory definition of fair market value, particularly as it applied to real estate is troubling, and could result in an unconstitutional taking of property since the limitations reduce the value of the property below fair market value as it is usually determined. The Phase I Regulations solve the issue by providing that a rental payment does not take into account its intended use if it takes into account costs incurred by the lessor in developing or upgrading the property.[81] In other words, a landlord can charge for the special fixtures or improvements required for a medical office. However, the Phase I Commentary indicates that the rental payments would not meet the fair market value test if the lessee pays an inflated rate solely to enhance his or her medical practice.

The Phase I Commentary also provides that fair market value can be determined by comparables; however, the comparables should not involve entities in a position to make referrals. The Phase I Commentary interprets the prohibition about payment for proximity under real estate rentals by providing that "We interpret this requirement to allow rental payments that reflect the fair market value of the area in which the property is located, even if the lease is for medical property in a 'medical community.' To qualify, the payments should not reflect any *additional* value, such as an amount that is above that paid by other medial practitioners in the same building or in a similar location, just because the lessor is a potential source of referrals to the lessee."[82]

The Phase I Commentary also state that DHS revenues can be taken into consideration when valuing a medical practice that is to be purchased or sold, so long as the DHS services meet the Stark in-office ancillary services requirements, discussed later in this Section.[83]

Although the Phase II Regulations do not change the definition of fair market value, they add a "safe harbor" for the determination of hourly compensation paid to a physician, and add other clarifying comments.

The Phase II Safe Harbor provides that hourly compensation paid for a physician's personal services (not including services performed by the physician's employees or others) is fair market value if it is determined by one of two stated methodologies:

- The hourly rate is equal to or less than the average hourly rate paid to emergency room physicians in the market when there are at lease three hospitals with emergency rooms in the market; or
- The hourly rate is determined by averaging the 50th percentile national compensation level for physicians in the same physician specialty (or in general practice if the physician's specialty is not in an approved survey) in at least four of six identified surveys divided by 2,000.[84]

The Phase II comments include:

> [T]he definition of "fair market value" in the statute and regulation is qualified in ways that do not necessarily comport with the usage of the term in standard valuation techniques and methodologies. For example, the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another.[85]
>
> [P]ayments for the non-compete covenant must be at fair market value. (We note that, in some contexts, these covenants in conjunction with a lease arrangement may not be able to satisfy the special fair market value rules for leases of space and equipment.)[86]
>
> ***Practice Alert.*** *There are no grandfather provisions in Stark. Thus, lease arrangements with hospitals requiring exclusive relationships, hourly compensation arrangements with physicians, including medical director agreements, and similar arrangements should be promptly reviewed, and if necessary, brought into compliance prior to the Phase II Regulations becoming final.*

[5] Incident To Services

Incident to services are defined in the Phase I and Phase II Regulations as those services that meet the requirements of section 1861(s)(2)(A) of the Social Security Act and section 2050 of the Medicare Carriers Manual (part 3), which define these services as being items or services furnished by the physician or "furnished under the physician's direct supervision."[87]

"Incident to" within the meaning of section 1861(s) (2) (A) of the Social Security Act and section 2050 of the Medicare Carriers Manual (part 3) encompasses both services and supplies (including drugs and biologicals).

The Carrier's Manual provides that to be covered, incident to the services of a physician, services and supplies must be an integral, although incidental, part of the physician's professional service, commonly rendered without charge or included in the physician's bill, of a type that are commonly furnished in physician's offices or clinics, furnished under the physician's direct personal supervision; and furnished by the physician or by a supervised individual who is an employee or contractor of the physician.

The Carrier's Manual provides that for services or items to be incident to, the charges for the services or items must be included in the physician's bills. Section 2050.1 of the Carrier's Manual (part 3) provides:

> Charges for such services and supplies must be included in the physician's bills…To be covered, supplies, including drugs and biologicals, must represent an expense to the physician. For example, where a patient purchases a drug and the physician administers it, the cost of the drug is not covered.

For drugs and biologicals to be covered as incident to services, they must be of the type that cannot be self-administered.[88] Incident to services performed by individuals other than the physician require that there be a physician service rendered to which the services of the auxiliary personnel are an incidental part.

Direct supervision requires that the physician be present in the office suite and available for immediate consultation. However, in a "physician-directed clinic" the supervision can be provided by another physician within the clinic. [89] A physician directed clinic is one where (a) a physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open; (b) each patient is under the care of a clinic physician; and (c) the non-physician services are under medical supervision.[90]

The Phase I Commentary also observes that CMS believes that the heightened supervisory requirements of group practice physicians for incident to services "provides some assurance that the 'incident to' DHS will not be the primary incentive for the referral."[91]

It is important to note that incident to services can only be included in productivity bonuses of group practice physicians. [92] Thus, compensation paid to physicians for their personal productivity as independent contractors under the "personal services arrangement" exception or as employees under the "employee" exception must be limited to the fair market value of the services they personally perform.[93]

The Phase I Commentary notes that CMS is concerned that physicians may over-influence non-physician practitioners who are licensed and capable of billing in their own right, such as nurse practitioners, switching their activities to incident to services, which can be used in the determination of physician compensation. CMS believes that the direct supervision requirements for incident to services will prevent abuse among physicians billing the services of these support practitioners as if their services were physician-performed services. For the services of nurse practitioners and other employees who have the right to prescribe

drugs or provide other DHS not be considered a physician referral, the employee must not only have the legal right to provide the item or service, the employee must not be directed or influenced to provide the item or service by the physician for whom he or she works.[94]

As we noted in our prior discussion of compensation, a *group practice physician's* compensation can include productivity bonuses based "directly on the physician's personal productivity (including services incident to such personally performed services)."[95]

[6] Patient Care Services

The definition of *patient care services* was expanded in the Phase I Regulations from that proposed in the 1998 Proposed Stark Regulations.[96] Patient care services include any tasks performed by a group practice physician that address the medical needs of patients whether or not patient encounters are involved, including time spent in consultation with other physicians, reviewing laboratory tests, training staff members, buying equipment and performing administrative services. The significance of the expanded definition is that it will be easier for physicians to meet the Stark definition of service required of members of a group practice.

[7] Physician in the Group

Independent contractor physicians who are not practice owners will not be considered members of a group practice. However, an independent contractor physician can be a *physician in the group* during the time-period he or she is providing services for the group to its patients in its facility. [97] The group's contract arrangement with the independent contractor physician must contain the same compensation restrictions that apply to group practice physicians under 42 C.F.R. §411.352(g), meet the personal service arrangement requirements of Stark (42 C.F.R. §41.357(d)), and must comply with the Medicare reassignment rules (42 C.F.R. §424.80(b) (3)). Referrals from the physician in the group are subject to the referral prohibition in 42 C.F.R. §411.353(a). The net effect is that the independent contractor employed by a group practice under a personal services arrangement can make DHS referrals within the group and provide supervisory services under the in-office ancillary services exception for services referred to him or her and, for the most part, be compensated as if they were physician members of the group practice, including compensation for "incident to" services, discussed in our Group Practice discussion below.[98]

[8] Set in Advance

With limited exceptions applicable to group practice profit sharing and productivity bonuses discussed later in this document, Stark prohibits compensation arrangements that are based directly or indirectly upon the volume or value of referrals. In some instances, a further restriction requires that compensation be *set in advance*. These include compensation payable to contractors under the "personal services" arrangement, compensation paid under the "fair market value" exception, and compensation paid by

"academic medical centers."[99] It also includes the "rental for office space" and the "rental for equipment" exceptions.

Phase II Regulations define "set in advance" [100] Compensation is "set in advance" when the compensation methodology:

- Is set forth in an agreement prior to the rendition of services.
- Can be independently verified.
- Is not changed during the course of the agreement in any way that reflects the volume or value of services or "other business generated" by the referring physician.

A significant improvement brought about by the Phase II Regulations was the removal of the prohibition to percentage compensation that appeared in the Phase I Regulations. Percentage compensation can be paid for personal services without violating the "set in advance" requirements when the arrangement satisfies the requirements stated above. Percentage compensation for personal services that meets the volume or value requirements of §§411.354(d) (2) and (3) would also satisfy those provisions, including their application to indirect compensation. (The Phase II Commentary includes an example of percentage royalty payments as not varying with the value or volume of referrals or other business generated.[101] The Commentary, however, cautions that per unit and per time compensation arrangements can violate the Anti-kickback Statute. If so, the exceptions under Stark would not be available.)

[9] Volume or Value of Referrals or Other Business Generated.

For the most part, Stark prohibits physicians from being compensated on the basis of the *volume or value* of referrals or *other business generated*.[102] These rules do not apply to personally performed physician services, since such services do not involve a referral.

Time-based or unit-of-service based compensation (which may include percentage compensation, although, beyond personal services, the Regulations are not clear) is not deemed to be compensation which takes into consideration the value or volume of DHS referrals when the compensation is fair market value and the compensation formula does not vary over the term of the agreement based upon the volume or value of referrals or other business generated.[103]

Other business generated includes non-DHS business (such as private pay insurance) generated by the referring physician that is not personally performed by the referring physician. Though personal physician services are excluded (no referral), included are the corresponding technical fees. The "per unit" and "per time" exceptions are not restricted by the "other-business generated" definition when the other-business compensation formula is fair market value and the formula does not change during the relationship.[104]

Phase II Regulations modify the Phase I Regulations that provide that the volume or value limitation does not prohibit physician compensation from being conditioned on

referrals of patients to a specific provider, practitioner, or supplier. Arrangements requiring a physician to refer to a particular DHS entity are permitted under 42 C.F.R. §411.354(d) (4) when the arrangement is:

- "Set in advance" for the term of the agreement,
- Consistent with "fair market value" (does not vary with volume or value of referrals),
- Permits the referral requirement to be negated if the patient (or the patient's insurer) expresses a different choice, or if the referral is not in the best interests of the patient in the judgment of the physician,
- Limited solely to the physician's services covered in the scope of the agreement,
- Limited to arrangements with employers, managed care plans, and certain contract arrangements, such as emergency physician agreements.
- Reasonably necessary to effectuate the legitimate purpose of the compensation arrangement.[105]

The Phase II Regulations also point out that these arrangements could violate the Anti-kickback Statute.[106]

Ironically, the position of the OIG is that the Anti-kickback Statute is violated when *any purpose* of a transaction is for making referrals. How enforcement of the Anti-kickback Statute will be resolved with the increased Stark Stature liberality is not known.

[10] Isolated Transaction

Phase II Regulations revise the 1998 Proposed Regulations defining an *isolated transaction* to permit installment sales and purchases of equipment and practices.[107] This important definition is discussed later in this paper.

[E] Group Practices

Certain of the Stark exceptions are particularly relevant to medical group practices and in order to qualify for those exceptions the medical group practice must satisfy the Stark requirements for a group practice. With the adoption of the Stark group practice requirements into the 1999 Final Safe Harbor Regulations under the Anti-Kickback Statute, compliance with the group practice requirements has significance beyond Stark.

[1] Statutory Definition of Group Practice

Under the Stark Statute, a group practice is a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan or similar association:

- In which each physician who is a member of the group (for this purpose, members include owners and employees) provides substantially the full range of services which the physician routinely provides, including medical care, consultation,

diagnosis or treatment, through the joint use of shared office space, facilities, equipment and personnel;
- For which substantially all of the services of the physician-members are provided through the group, are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group;
- In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined;
- Except as permitted by a special exception for sharing of profits or the payment of productivity bonuses, in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician;
- In which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and
- Which meets such other standards as the Secretary may impose by regulation.[108]

Under the Stark Statute, a group practice physician may be paid a share of overall profits of the group or a productivity bonus based on services personally performed, or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which "directly" relates to the volume or value of referrals by the physician.[109]

The Regulations clarify and modify the group practice requirements in several respects, discussed in the sections below.

[2] Group Practice Single Entity and Entity Ownership

Under the Regulations, a group practice must be organized and operated as a single entity, which could be a proprietorship, partnership, corporation, limited liability company, or other entity authorized by law.

Under the Regulations, a group practice can be owned by almost any person. The group practice can be owned by one physician, more than one physician, or by non-physicians, as long as two or more physicians have a role in providing patient care services and all of the physicians are employed by a single entity engaging in the group practice; however, a group practice cannot be owned by another *active* group practice, and an informal affiliation of physicians formed primarily to share referrals or separate group practices under common ownership or control through a PPM, hospital or other organization does not meet the single entity requirement.[110]

Phase II Regulations added a provision to 42 C.F.R. §411.352(a) that allows multi-state, parallel entities to count as a single-entity group practice when state law requires separate entities in each state.[111]

It should be noted that the 1999 Final Safe Harbor Regulations under the Anti-kickback Statute provide a safe harbor only for group practices *owned exclusively by physicians*.

Thus, group practices owned by hospitals, PPMs, or other health care providers will not fall under the safe harbor.

[3] Primary Operation

The primary business of an entity practicing medicine as a group practice must be a medical practice. Specifically noted in the Regulations is that a hospital employing physicians is not a group practice, because its primary method of operation is not as a medical practice. A hospital, however, when permitted by state law, can own a subsidiary that practices medicine and that entity would qualify as a group practice. The Phase II Regulations removed the requirement that the entity be "formed" for the purpose of practicing medicine and clarified that the relevant inquiry is into its method of operation.[112]

[4] Members of the Group

A group practice must have at least two physicians who are members of the group.[113]

A group practice could consist of physicians employed part-time and full-time if the other group practice tests are met.[114]

A physician is a member of the group if he or she is an owner of the group practice directly or indirectly (through another entity) or if he or she is employed as a common law employee by the group practice. A physician is a group practice member during the time the physician provides patient care services for the group. Also included as group members are *locum tenens* and "on-call" physicians while providing service. Independent contractors and leased employees are not group members; however, Phase II Regulations added an important clarification in the definition of *member of the group*. A leased employee (in most states, a "statutory" employee) meeting the common law definition of employee with the practice is a member of the group.[115] A leased employee owner would also be a group member.

> ***Practice Alert.*** *Employee leasing is becoming an important method for human resource management. When physicians are leased, their employment agreements with the practice should indicate the leasing arrangement is an accommodation to the practice and is not intended to, and does not, change the common law employment arrangement between the physician and the practice.*

[5] Range of Care

Each group physician must furnish through the group substantially the "full range" of patient care services that the physician routinely furnishes.[116] If the physician works for only one practice, then the full range of services is provided, regardless of what is done;

however, if the physician works in other practices also, then the range of services provided within and outside the practice must be substantially the same.

[6] Amount of Services Provided by Group Members

Substantially all of the patient care services provided by the group practice must be provided by members of the group. This requirement is met when the group practice physicians provide and bill at least 75% of the total patient services of the group practice members under one or more provider numbers assigned to the group. Amounts received for the services must be treated by the group as group practice receipts.

The 75 % test is measured by the total time physician members spend providing "patient care services" as defined in the Regulations, documented by any reasonable means, such as time cards, appointment calendars or diaries. For example, if a physician works full-time in a group practice (100%) and another physician works half-time (50%) in the same practice, the 75 % average requirement is met.

The 75% test can also be measured by any alternative measure that is reasonable, fixed in advance and consistently used over the measurement period.[117] Practices are required to make the records available to the government upon request. Services within a HPSA area by group practices located outside the HPSA area do not count in the measurement. Time spent at "free clinics" can also be ignored.[118]

[7] Start-Up and New Member "Phase-In" Time

The Regulations allow a newly-formed group practice a "start-up" phase–in up to 12 months, as long as the group practice makes a good faith effort to comply with the 75% services requirement described above, and does comply by the end of the 12-month period. The Regulations provide that the start-up provisions do not apply to reorganized, purchased, or merged group practices, and do not cover the admission of new members.[119] However, Phase II Regulations also permit a phase-in for a new group practice member who "relocates" his or her practice as defined in the "recruiting agreement" exception contained in 42 C.F.R. §411.357(e)(2).[120] The relocation does not have to occur under a hospital-assisted recruitment, but the relocation must meet the recruiting exception's relocation test.

[8] Patient Encounters

The Regulations include the requirement that members of the group must personally conduct not less than 75% of the physician-patient encounters of the group. For this purpose, independent contractor encounters, even if the contractors are considered physicians "in the group" for purposes of referrals, in-office ancillary services supervision and compensation, do not count.[121]

[9] Group Practice as a Unified Business

The Group Practice Investor Safe Harbor Regulation to the Anti-Kickback Statute adopted the Stark group practice definition and added a further complexity by providing that group practices with satellite office accounting for profits and expenses will not qualify for the safe harbor. The Phase I Regulations adopt a more realistic, easier-to-meet standard for the group practice business. Under the Phase I Regulations, a practice will meet the unified business requirement if it has the following two features:

- Centralized decision-making by a body representative of the group that maintains effective control over the group's assets, liabilities, budgeting, compensation and salaries.
- Consolidated billing, accounting, and financial reporting.

The requirement for "centralized utilization review" contained in the Phase I Regulations has been removed, since CMS concluded most practices do not do that.[122]

The unified business test provides that a group practice will meet the test even if it provides non-DHS and DHS location or specialty-based compensation and profit sharing practices, provided the DHS compensation and profit sharing practices meet the "special rule for productivity bonuses and profit shares" provided under 42 C.F.R. §411.352(i), discussed next.

Structuring a group practice entity must take into consideration the requirement for centralized decision-making. The Phase II Commentary indicates that no particular form of management centralization is required; however, the Commentary points out:

> [T]he centralized management of the group practice must exercise substantial control over the process and output of these activities and not simply rubber stamp decisions of various cost centers and locations.[123]

Although Stark restrictions apply only to referrals for DHS services, when determining whether a group practice is functioning as a total business, the group's methods of distributing revenues from all sources is considered.[124]

[10] Special Rule for DHS Productivity Bonuses and Profit Shares

Contrary to the Safe Harbor Regulations and the 1998 Proposed Stark Regulations, the Phase I Regulations specifically permit location and specialty-based compensation practices with respect to non-DHS revenues and permit location and specialty-based compensation practices for DHS revenues that meet special rules for DHS-related productivity bonuses and profit shares.[125]

The special rules provide that a physician in a group practice may be paid a share of the overall profits of the group or a productivity bonus based upon services he or she actually performed (including incident to services) provided that the share or bonus is not

determined in any manner that is *directly* related to the volume or value of DHS referrals by the physician. Phase II Regulations clarified that incident to services could be utilized and confirm that a group practice can use the special rules to pay employees, members and independent contractors qualifying as "physicians in the group practice."[126]

For purposes of the rule, "over-all profits" means the entire profits derived from DHS payable by Medicare of the group or of a component of the group that has at least five physicians. The profits must be divided among the component group on a "reasonable and verifiable basis" that is not based on referrals. Safe harbors are provided for profits distributed per capita basis or on the basis for the distribution of revenues that are non-DHS.[127]

However, if the DHS revenues are less than 5% of the group practice's total revenues and the allocation to any physician is less than 5% of his or her total compensation there is no restriction on the method of allocation.

A productivity bonus should also be based on a "reasonable and verifiable" basis not based on referrals. A safe harbor is provided when the bonus compensation is based upon the physician's total patient encounters (RVUs) or the bonus is based upon the allocation of the physician's compensation attributable to non-DHS services. [128] Again, if the total practice DHS revenues are less than 5% and the allocation to the physician is less than 5% of his or her compensation, any method can be used.

Practices are required to maintain supporting documentation verifying the method used in the calculation of profit share and bonuses.

The Phase I Commentary contains the following explanation, which limits the application of the special compensation rules to directly-performed and incident to services:

> Accordingly, we have revised the regulation to make it clear that group practices may pay member physicians (and independent contractors who qualify as "physicians in the group") productivity bonuses based directly on the physician's personal productivity (including services "incident to" such personally performed services that meet [the incident to tests]), but not pay these physicians any bonus based directly on their referrals of DHS that are performed by someone else."[129]

As we noted in our discussion of the definitions of compensation and incident to services, incident to services must be included in the physician's bill.[130] The Phase I Commentary noted that CMS believes that the heightened supervisory requirements for incident to services "provides some assurance that the 'incident to' DHS will not be the primary incentive for the referral."[131]

The Phase I Commentary indicates that physicians can be paid directly on their personally performed and incident to services. The Stark Statute itself is more limiting, and states:

> A physician in a group practice may be paid a share of the overall profits of the group, or a productivity bonus based on the services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.[132]

The only change in the Regulations is to insert "of DHS" after "referrals."[133]

[11] Volume or Value of Referrals

The group practice regulations require that no group practice member can be compensated directly or indirectly for the value or volume of referrals. By definition, distributions under the "special rule for productivity bonuses and profit share" discussed in the preceding paragraph are not deemed to be based on the volume or value of referrals.

[12] Group Practice Distribution of Income and Expense

The Stark Statute and the Regulations require that group practice expenses and income be distributed "in accordance with methods previously determined."

The Commentary to the 1998 Proposed Stark Regulations expresses concern that the statutory definition, as implemented by the Regulations, could be interpreted to allow a group practice to determine its method of income distribution on an *ad hoc* basis, shortly before the income is distributed. Making the income allocation decisions at the time income is distributed, the government believed, allowed the physicians to skew the distribution of income to favor compensation for physicians' referrals. Therefore, the 1998 Proposed Stark Regulations required that both overhead expenses and income of a group practice be distributed according to methods that are determined before the period during which the group has earned the income or incurred the costs.[134]

The Phase I Regulations make several important improvements. Under the regulations, the overhead expenses and income of the practice must be distributed according to methods determined before the *receipt* of payment for the services. Thus, practices can be decisions based upon cash basis accounting rather than accrual accounting. The Phase II Commentary clarify that the group practice can adjust its compensation plans prospectively at any time, as long as any change is subject to the restrictions on the distribution of DHS revenues contained in 42 C.F.R. § 411.352(i).[135]

[F] Statutory Exceptions

The exceptions to the Stark Statute's referral prohibition are discussed below. Certain of the exceptions are applicable to both compensation and investment arrangements; others are applicable only to one arrangement or the other, but not both.

The primary statutory exceptions that apply to both compensation and investment arrangements are the "physician services exception" and the "in-office ancillary services" exception. In addition to addressing the statutory exceptions, the Regulations added new regulatory exceptions that apply to both compensation and ownership arrangements and new exceptions that apply only to compensation arrangements. The Regulatory exceptions are discussed in section [G] of this paper.

[1] Physician Services Exception

The Stark Statute and the Regulations provide that *physician services* are an exception to both the compensation and ownership arrangement prohibitions when the physician services are provided personally (or under the personal supervision of) another physician in the same group practice as the referring physician.[136] These services do not have a location limitation (in the office) as does the "in-office ancillary services" exception.

Physician services are defined in 42 U.S.C. § 1395x (q) and include surgery, consultation, and home, office and institutional calls. Section 410.20(a) of the Regulations includes the above definition and adds diagnosis and therapy services to the physician services definition.

The Phase II Commentary clarifies that antigens, which are paid for by Medicare as physician services, are included in this exception.[137]

For the purpose of the physician services exception, the Regulations provide that "incident to" services are limited to the "physician services" portion defined in 42 C.F.R. § 410.20(a). Thus, other "incident to" services, such as diagnostic tests and physical therapy, are outside the physician services exception.[138]

What this bifurcation in the application of the "incident to rules" indicates is that DHS services performed incident to the physician's services performed under the exception must fall under the in-office ancillary services exception discussed next.

When a physician provides services for his or her group practice under the physician service exception, the special rules for productivity bonus and profit share reviewed in our earlier discussions of group practice compensation apply to the incident to DHS services not included as part of the physician's services under this exception. Thus, the general rule permitting physicians to be directly compensated on their production, including incident to services, are limited in the case of services provided as a group practice physician.

The Commentary concludes that this exception is of limited application, providing protection to the "narrow class of physician services that are included in the definition of DHS, especially in the area of radiology." The Phase I Regulations extend the physician services exception to include the services of independent contractors who qualify as "physicians in the group."[139]

[2] In-Office Ancillary Service Exception

The Stark Statute and the Regulation *in-office ancillary services* exception applies to both the compensation and investment prohibitions.[140] The exception is applicable to all DHS other than durable medical equipment (excluding infusion pumps and certain other items specified in the regulations) and parenteral and enteral nutrients, equipment and supplies. The Phase II Regulations substantially liberalize and clarify the in-office ancillary services exception, making provision for part-time use of offices and permitting less non-DHS services at those offices.

> ***Practice Alert.*** *Although the Phase II Regulations liberalize the definition of "same building" and permit the part-time use of a building, care must be taken to coordinate use of the primary building (open 35 hours a week, with 30 hours of physician use) and a branch building (open 8 hours a week, with 6 hours of physician use).*

[a] In-Office Ancillary Services Regulatory Criteria

To meet the in-office ancillary services exception, the following criteria must be satisfied: [141]

1. The DHS services must be furnished personally by: (a) the referring physician, (b) a physician who is a member of the same group practice as the referring physician or (c) individuals who are supervised by the referring physician or another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services.

2. The DHS services must be "furnished" in one of three locations:
   2.1. The *same building* (as defined in §411.351 and below) , but not necessarily in the same space or part of the building, in which meets all of the conditions of one of the following three tests —
      2.1.1. The referring physician or his or her group practice has an office that is normally open to the physician's or the practice's patients for medical services at least 35 hours per week, and the referring physician or one or more members of the group practice regularly practice medicine and furnish physician services to patients at least 30 hours per week. The 30 hours of services must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal payer or a private payer, even though the physician services may lead to ordering DHS; or
      2.1.2. The patient receiving the DHS usually receives physician services from the referring physician or members of his or her practice and the referring physician or his or her practice rents or owns an office that is normally open to the physician's or the group's patients at least 8 hours per week and the referring physician regularly practices and furnishes physician services at least 6 hours per week. The 6 hours of services must include some physician

services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal payer or a private payer, even though the physician services may lead to ordering DHS; or

2.1.3. The referring physician is present and orders DHS during a patient visit on the premises as set forth in (i) and (ii) above, or a member of the referring physician's group practice is present on the premises while the DHS is administered. The office must be owned or rented by the physician or the practice at least 8 hours a week and the referring physician or one or more members of the group practice furnishes physician services 6 hours a week. The 6 hours of services must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal payer or a private payer, even though the physician services may lead to ordering DHS.

2.2. In a *centralized building* (as defined in §411.351 and below) that is used by the group practice for the provision of some or all of the group's clinical laboratory services, or

2.3. In a *centralized building* that is used for some or all of the group's DHS (other than clinical laboratory services).

3. The DHS services must be billed by one of the following:
   3.1. The physician performing or supervising the services,
   3.2. The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice,
   3.3. The group practice, if the supervising physician is a "physician in the group" under a billing number assigned to the group,
   3.4. An entity that is wholly owned by such physician or the group practice under the entity's billing number or a number assigned to the physician or group, or
   3.5. An independent third-party billing as agent for the physician, group practice or entity described above under their billing number.

The Phase II Commentary explains the hours specified in the "same office" requirement and the amount of non-DHS business that must be done in the following way:

> This [hourly] standard is not intended to preclude use of in-office ancillary services exception by … practices that have unfilled appointment slots, cancellations, or other occasional gaps in the furnishing of services…. Rather they must regularly (that is in the customary, usual, and normal course) practice medicine in the building for the minimum number of hours….We are not requiring any particular threshold amount of physician services unrelated to DHS.[142]

The Phase II Commentary also points out that the new "building" requirements do not prevent a medical practice from purchasing the "technical components of mobile services (which are not buildings for purposes of the in-office ancillary services exception) and bill for them under §411.50 and the purchased diagnostic testing rules at section 3060 of the Medicare Carriers Manual…"[143] The purchased diagnostic testing rules would

prohibit markup, and the physicians must accept the lowest of the physician fee schedule, the physician's actual charge or the supplier's net charge for the test.[144]

The DHS in-office ancillary services may include canes, crutches, walkers, folding manual chairs and blood glucose monitors that are used outside the physician's office when certain conditions specified in the Regulations are met.[145] (For example, the cane must be given in the same office and must be necessary for the patient to leave the office. The physician who is a DME supplier must meet the supplier standards located in §424.57(c).)

Contrary to the 1998 Proposed Regulations, the Regulations do not require that these items be sold to patients at cost.

The Phase I Regulations and the Phase II Commentary clarify that prescription drugs provided in the office, though used at home, fell under this exception, as did external ambulatory infusion pumps and chemotherapy infusion drugs when administered or dispensed to patients in the physician's office. The Regulations also liberalized the "direct" supervision requirement of the Stark Statute by defining the supervision requirement as that being applicable under Medicare payment or coverage rules. The Regulations also make it clear that a physician in a non-group practice must provide the direct supervision and cannot delegate it to a contractor physician.[146]

[b] DHS "furnished"

DHS is furnished under this exception at the place the service is performed upon a patient, or the item is dispensed in a manner that meets the Medicare payment and coverage rules.[147] The objective stated in the Regulations is that the DHS "qualifying for the exception is truly ancillary to the physician's core medical office practice and is not provided as part of a separate business enterprise."[148]

[c] Building Defined

Under the Regulations, the *same building* is defined as a structure or combination of structures sharing the same post office address, excluding the exterior space such as the parking lot, driveways and lawn, and excluding interior parking garages.[149]

The Regulations include a special definition of the same building to permit physicians to treat patients in their homes. The special provision specifically states that the personal residence of a patient does not include a nursing home, long-term care or other institutional facility, but could include an assisted or independent living facility.[150] The personal residence "exception" requires that the physician be present in the home at the commencement of the DHS service.[151]

> ***Practice Alert.*** *The liberalization of the "same building requirements" was intended to meet the requirements of radiologists and oncologists who frequently "ride a circuit" CMS believes that these specialties could meet the requirements by providing "some" unrelated DHS*

> *services at the various offices. Practices that do in fact "ride a circuit" will have to redo their part-time lease arrangements when, for example, the offices are for a Wednesday afternoon. That will not be enough time if DHS is provided at the office. The office must be open 8 hours a week, and must provide 6 hours of weekly services from the sublessee doctors.*

A *centralized building* is defined as all or part of a building that is used exclusively by a group practice. A centralized building could include a mobile vehicle, van or trailer that is owned or leased on a full-time basis (24 hours a day, 7 days a week for at least 6 continuous months) when it is exclusively used by the group. Shared space in a building or a mobilized vehicle is not centralized if it is shared with another practice.[152] A group practice may have more than one centralized building.

A non-group practice cannot use a centralized building for its DHS. A group practice may provide DHS services to other providers from its centralized building when the providers purchase the DHS services.[153] (However, state laws, like the Florida Patient Self-Referral Act of 1992, frequently prohibit the practice from selling DHS to other practices.)

The requirement that the centralized building be used on a full-time basis prohibits the part-time rental of facilities for DHS. For example, a common practice of a clinic renting space and technical personnel in a radiology office on a part-time basis so that the clinic could provide MRI services to its patients is not permitted under the Regulations.

[b] Billing Requirement

As noted above, the in-office ancillary services exception requires that ancillary services be billed by (1) the physician *performing or supervising* the performance of the services, (2) a group practice of which that physician is a member under a billing number assigned to the group practice, or (3) an entity that is *wholly-owned* by the physician or group practice.

Group practices may have more than one billing number. When practices bill through a separate entity, the entity must be wholly owned and cannot be owned as a joint venture. Independent contractors who are "physicians in the group" for supervisory purposes cannot bill for themselves; they must assign their billing responsibilities to the group.[154]

The 1998 Proposed Stark Regulations Commentary stated that if a group practice physician bills under his or her own Medicare provider number for DHS, the individual will be considered a "solo practicing physician" for that service. Physicians are considered members of the group only "during the time they furnish services to patients of the group practice that are furnished through the group and billed in the name of the group.... If a physician bills for a service independently, other group members cannot directly supervise those services."[155]

The 1998 Proposed Stark Regulations Commentary also concluded that separate billing by a group practice physician could cause the group to fail the "substantially all" test. This test requires substantially all of the group practice services to be provided by the practice itself. The Phase I Regulations adopt the same position:

> We also believe that any services the physician bills in his or her own name are not group services and, therefore, should be factored into the "substantially all test" as outside patient care services.[156]

[3] Publicly Traded Securities Exception and Other Ownership Exceptions

The Stark Statute and the Regulations create an ownership exception for *publicly-traded securities and mutual funds*.[157] Ownership of investment securities (including shares bonds, debentures, notes, or other debt instruments) in a DHS entity by a physician that may be purchased on terms generally available to the public are permitted when the securities are listed on a recognized stock exchange publishing quotations on a daily basis, or are traded under an automated interdealer quotation system. However, this exception is only available when the corporation whose securities are at issue has *stockholder equity* exceeding $75 million based upon the most recent fiscal year or the past three fiscal years average. The Stark Statute also permits ownership of share in a mutual fund with *total assets* exceeding $75 million based upon the most recent fiscal year or the past three fiscal years average.

The Phase II Regulations and Commentary clarify that the ownership test is measured at the time of the DHS referral and not at the time the securities are acquired.[158] Thus, physicians can obtain securities in private companies or offerings of small public companies, so long as no DHS referrals are made until the securities are generally available to the public and the net worth tests are met. Furthermore, since stock options are generally considered compensation arrangements and not investment or ownership interests, physicians could have fair market value stock options as part of a compensation arrangement with DHS companies where the price of the shares does not vary with the value or volume of referrals. Once exercised, however, the securities obtained under the options become ownership interests.[159] These arrangements, however, may raise issues under the Anti-kickback Statute.

The Stark public company test is different from the Public Company Investment Interest Safe Harbor contained in the Anti-Kickback 1999 Final Safe Harbor Regulations, discussed in the preceding section. The Safe Harbor has a $50 million standard, based upon the book value of the net assets of the entity invested in the delivery of health care goods and services.

Stark also permits physician ownership in "special providers," which are (i) a rural provider (an entity that provides not less than 75% of its DHS to residents of a rural area and for 18 months after December 8, 2003 is not a specialty hospital), (ii) a hospital located in Puerto Rico, and (iii) a hospital located outside of Puerto Rico when the physician is authorized to perform services at the hospital, the ownership interest is in the

entire hospital, and for a period of 18 months after December 8, 2003, the hospital is not a specialty hospital.[160]

The non-specialty hospital ownership exception is based upon the DHS being furnished by the hospital and not a hospital-owned entity, such as a SNF. A "hospital" is an entity that meets the Medicare tests for participation in the program as a hospital. Ownership in a holding company that owns a chain of hospitals would qualify. Ownership in a part of a hospital will not. The Phase II Commentary is quick to warn physicians that ownership in a hospital, though permitted by Stark, raises Anti-kickback Statute concerns.[161]

In addition, a new regulatory exception has been created for entities with which the physician has a financial relationship in regard to certain DHS rural area referrals when there is no DHS entity within 25 miles of the patient's residence. [162] This exception is discussed later in this paper. CMS also included a new limited exception for rural-area referrals between physicians within the same family.[163] This exception is discussed later.

CMS specifically rejected the idea of permitting continued investment in providers who, because of changes in population, loose status as rural providers. [164]

> ***Practice Alert.*** *Because Stark provides no grandfathering of investments, physicians who own investments that do not qualify cannot make DHS referrals to the entity in which the ownership exists. If a physician owned a qualified interest which later becomes unqualified, the interest must be disposed of within 90 days under a new regulatory exception, discussed later in this paper.*

[4] Bona Fide Employment Arrangements Exception

The Stark Statute and Phase II Regulations provide that *bona fide employment relationships* exception for physicians and immediate family members is a compensation exception.[165] The exception is met when:

- The employment is for identifiable services;
- The amount of the remuneration under the employment—
  - Is consistent with the fair market value for the services, and
  - except as determined in paragraph 4 below is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,
- The remuneration is provided pursuant to an agreement that would be commercially reasonable even if no referrals were made to the employer; and
- productivity bonuses based on services personally performed by the physician or immediate family member are permitted (no referral).

Productivity bonuses under this exception cannot be based upon "incident to" services. The employee must meet the common law tests of employment. The employment arrangement may include referral restrictions, previously discussed in this paper.[166]

Employment agreements may contain covenants not to compete; however, if there is compensation allocated for the covenant, the compensation must be fair market value. [167]

> ***Practice Alert.*** *The Phase II Commentary clarifying discussions about covenants not to compete raise issues when structuring a purchase of a physician's interest in a practice when the selling physician continues to render services, even transitional services. Essentially, the Phase II Isolated Transactions Exception, against the background of the Commentary about covenants, affirms the importance of proper determination and allocation of any practice purchase price if the selling physician remains in a position to make referrals.*

The more restrictive *bona fide* employment exception should not be used when the physician services qualify under the "physician services" exception or for the "in-office ancillary services" exception. Compensation may also be based upon quality factors, so long as the overall compensation is fair market value and not based upon referrals.[168]

[5] Space and Equipment Lease Exceptions

Space and equipment lease exceptions are compensation exceptions, not investment exceptions, under the Stark Statute.[169]

The Stark Statute provides that the leases of office space or equipment exceptions are met when the following conditions are satisfied:

- The lease is set out in writing, is signed by the parties, and specifies the premises (or equipment) covered by the lease;
- The space (or equipment) leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease and is used exclusively by the lessee when being used by the lessee; except that, in the case of space leases, the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's *pro rata* share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas;
- The lease provides for a term of at least one year;
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

- The lease would be commercially reasonable even if no [DHS] referrals were made between the parties; and
- The arrangement meets such other requirements as the Secretary of HHS may impose by regulation as needed to protect against program or patient abuse.

The Phase II Regulations[170] make substantial improvement over the 1998 Proposed Stark Regulations, which provided that an excepted lease could only be canceled for cause and renewals must be for periods of at least one year, and which excluded capital leases.[171]

Under the Phase II Regulations, a lease can be terminated with or without cause during a lease term as long as no new agreement is entered into during the first year of the "original" lease term.[172] This provision is similar to the termination provision under the personal services exception, discussed next; however, this provision does not prohibit the parties from entering into same agreement following a termination, only from entering into new arrangements; in contrast, the personal services exception prohibits the parties from entering into the "same or substantially same" arrangement following termination, but do not prohibit a new arrangement.

All leases, capital or operating are permitted. A sublease is permitted when the sublease does not share the rented space or equipment with the sublessor during the time of the sublease (however, common area sharing would be permitted under space leases when the common area charges are appropriately prorated[173]). The Phase II Commentary caution:

> A subleasing arrangement may create a separate indirect compensation arrangement between the lessor and the sublessee that would need to be evaluated under the indirect compensation rules.[174]

The issue would arise if, for example, a hospital leases space to a practice, which in turn subleases space to another practice. If the sublessee-practice has privileges at the hospital, the sublease creates an indirect financial arrangement between the hospital and the sublessee, which could be an indirect compensation arrangement.

> ***Practice Alert.*** *Most medical office subleases lack the specificity required under the Phase II Regulations and will have to be adjusted. The Phase II Commentary specifically state that during the period examination rooms are used by a sublessee physician, they cannot be used by the sublessor. Furthermore, the rental for the use of waiting rooms and other common areas must be prorated. For safety, the sublease should identify the sublease space.*

The Regulations provide that rental charges cannot be based upon "other business generated," which term includes private pay insurance, but excludes personally performed services. [175]

The "volume or value" of referrals exception definitions discussed previously permit "per click" or "per time" lease arrangements that are fair market value. [176]

The Phase II Regulations also permit month-to-month holdover leases for up to six months as long as they continue the same terms and conditions as the original lease.

> ***Practice Alert.*** *State law, and most leases, provide for tenant holdover to be at some multiple, usually 2 or 3 times, the basic rent. If holdover is to be permitted under a lease, consideration should be given as to whether or not application of the holdover multiple of the basic rent violates Stark. The Regulations make no reference. Until the answer is known, leases should include a permitted six-month holdover provision at the same rent.*
>
> *Some commentators have interpreted the "set in advance" Phase II Regulation changes that permit percentage compensation as applying only to physician services arrangements and not to leases. Furthermore, percentage leases raise substantial anti-kickback issues.*

Fair market value has special definitions for lease arrangements, which are discussed under the "fair market value" definition section of this paper. Generally, fair market value of rental property is the rental value of the property for "general commercial purposes" not taking into consideration the property's intended use. When the lessor is a potential referral source, the general commercial value cannot take into consideration the additional value the prospective lessor or lessee would attribute to proximity or convenience.[177]

[6] Personal Services Arrangement Exception

The Stark Statute *personal services arrangement* exception is a compensation exception, not an investment exception. The exception is addressed in the Phase II Regulations. [178]

The personal services exception deals with physicians or family members who have independent contractor relationships with health care providers, as contrasted to employee relationships. The exception permits a physician to refer patients to an entity with which the physician has a personal services arrangement when the following conditions are satisfied:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;
- The arrangement covers all of the services to be provided by the physician (or an immediate family member of the physician) to the entity;
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of the arrangement is for at least one year;

- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a "physician incentive plan" is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- The arrangement meets such other requirements as the Secretary of HHS may impose by regulation as needed to protect against program or patient abuse.

A *physician incentive plan* is a compensation arrangement between a DHS entity (or downstream subcontractor) and a physician or group practice that may have the effect of limiting services.[179]

The Phase II Regulations add the right to terminate a personal services arrangement with or without cause so long the parties do not enter into the same or a similar arrangement during the first year of the *original* term of the arrangement.[180] Unlike the lease exception discussed in a prior section, this cancellation provision does not prohibit entering into new arrangements that meet the exception upon a first-year termination, only entering into the same or similar agreements following a termination during the first year of the original term. This does not appear to be a drafting error. The Phase II Commentary states that as long as any new agreement meets the requirements of the exception, there is little risk to Medicare.[181]

> ***Practice Alert.*** *As noted, this provision is similar, but not exactly the same, as the cancellation provision permitted in leases; it appears to allow cancellation (subject to the renegotiation limitation) at anytime beyond the initial term of the lease (renewals are not the original term of the arrangement), although, generally, an agreement's renewal is treated as a new agreement; thus, until clarified, we recommend that the first year non-renegotiation limitation be included for each renewal term. That approach is also more consistent with the Anti-kickback Safe Harbor.*

Phase II Regulations also modify the requirement that "all services" must be provided in the agreement documenting the arrangement. Separate agreements or arrangements are permitted so long as the DHS entity maintains a cross-reference list, or the agreements cross-reference each other. The list must be maintained for CMS inspection.

Thus, a hospital employing a physician's wife as a nurse and a physician as medical director will not have to have both arrangements documented in the same agreement.

The personal services can be provided through the physician's employees, wholly-owned entities or *locum tenens* physicians.[182] It is important to note, that although personal

services can be provided by a physician's wholly-owned company, they cannot be provided by a company when the physician or immediate family member is not the sole owner. The Phase II Commentary states that the objective is to prevent wholesale DHS services brokering under this provision.

The aggregate compensation under this arrangement need not meet the "set in advance" tests, although productivity compensation elements would have to meet the applicable set in advance requirements. The arrangement is not limited to physician services. For example, a medical director's agreement providing administrative services could utilize this exception.[183]

When compensating physicians under this provision, the Phase II definition of fair market value, and in particular the hourly rate safe harbors, must be considered. The Commentary points out that "cut-rate" management arrangements entered into in exchange for steering business do not meet the exception.[184]

[7] Isolated Financial Transactions Exception

The *isolated financial transaction* exception is a statutory compensation exception, not an ownership exception, and is available when the following conditions are satisfied:[185]

- The amount of the remuneration paid to a referring physician is consistent with fair market value (for example, the fair market value of the property or practice sold) and is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician;
- The remuneration is provided pursuant to an agreement that would be commercially reasonable even if no referrals were made by the physician to the other party involved in the transaction (such as the purchaser of the property or practice); and
- The transaction meets such other requirements as the Secretary of HHS may impose by regulations as needed to protect against program or patient abuse.

The 1998 Proposed Stark Regulations included the requirement that if a physician participates with another person in an isolated transaction, there must be no additional transactions between the parties for a period of six months after the isolated transaction except for transactions specifically excepted under other Stark exceptions. Thus, multiple isolated transactions between the same parties can be used when separated by at least a six months period. For example, instead of a physician selling a 50% interest to another physician in his or her practice in a single transaction, the selling physician could agree to sell 25% at one time and 25% a later time, so long as the six month interval is respected. Unlike the Sale of Practice Safe Harbor found in the Anti-Kickback Statute, the 1998 Proposed Stark Regulations concluded that an isolated transaction exception does not permit the installment sale arrangement of an asset or practice.[186]

Fortunately, the Phase II Regulations permit installment sales under certain circumstances, and otherwise adopt a more realistic view of this exception.[187] Under the Phase II Regulations, an isolated transaction is an exception when:

- The amount of the remuneration is consistent with the fair market value of the transaction and is not determined in a manner that takes into account, directly or indirectly, the value or volume of referrals by the referring physician or other business generated between the parties.
- The agreement is commercially reasonable even if the physician made no referrals.
- There are no additional transactions between the parties for 6 months after the isolated transaction except transactions that are exempt under §§411.355-357, and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

Isolated Transaction is defined in the Phase II Regulations as a transaction between two or more persons that involve a single payment or a series of integrally related installment payments when:

- The aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the value or volume of referrals or other business generated by the referring physician; and
- The payments are immediately negotiable or are guaranteed by a third party, secured by a negotiable note, or subject to a similar mechanism to assure payment in the event of the purchaser's default.[188]

The Phase II Commentary makes it clear that the isolated transaction is not limited to transactions related to DHS.[189] The Commentary also makes it clear that when both an employment arrangement and a practice sale arrangement are involved, they must each be measured under the separate exceptions that apply to them. [190]

> ***Practice Alert.*** *On occasions physicians or their advisors will want to structure a practice sale or buy-in so that a substantial portion of the arrangement is "pre-tax" and therefore deductible. Any such transaction taken as a whole will not meet the isolated transaction exception. The transaction must be measured by analyzing its elements. For example, the employment contract arrangements (paying deductible compensation) must be measured under the Regulations related to employment arrangement exceptions, including fair market value requirements. The portion of the transaction related to the actual sale must be measured under the isolated transaction exception, including its fair market value and terms of sale requirements. In addition, income tax regulations must be considered.*

[8] Remuneration Unrelated to the Provision of DHS Service.

The Stark Statute and the Phase II Regulations provide that *remuneration provided by a hospital to a physician that does not relate to the furnishing of DHS* is a compensation exception.[191]

This exception has been viewed as protecting many contractual arrangements between physicians and hospitals. However, the exception has been substantially narrowed by the Phase II Regulations and is now of little value. Under the Regulations, the exemption does not apply:

- To remuneration from a hospital to a member of a physician's immediate family.
- To remuneration from entities other than hospitals.
- The remuneration must be completely unrelated to DHS.

The last requirement added by the Regulations is very limiting. CMS regards any item that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles be related directly or indirectly to the provision of DHS.[192] The lease of office space in a medical building to physicians in a position to refer DHS is related. Payment of malpractice insurance premiums or other physician support services is related and this exception is not available for such items. A payment by a hospital for a covenant not to compete "is plainly related to the provision of DHS." The Phase II Commentary concludes by pointing out that the covenant may fit within another exception.[193]

> ***Practice Alert.*** *The limiting Phase II Regulations under this exception may exceed CMS' authority. The Stark Statute provides specific authority to CMS to provide regulatory amendments or interpretation to many of the provisions of Stark. Provisions frequently end with "the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse;" however, this exception does not include this kind of authority.*

[9] Physician Recruitment.

The Stark Statute and the Regulations provide an exception for recruiting agreements between physicians and hospitals[194] when the physician "relocates" his or her practice to the "geographic area" served by the hospital in order to become a member of the medical staff of the hospital when the following additional conditions are satisfied:

- The arrangement is set out in writing and signed by the parties.
- The arrangement is not conditioned upon hospital referrals from the physician.
- The hospital does not determine, directly or indirectly, the amount of remuneration to the physician based upon the volume or value of actual or anticipated referrals by the physician or the amount of other business done by the parties.

- The physician is allowed to establish hospital privileges at any other hospitals and to refer business to any other entity (except as referrals may be restricted in a separate employment agreement or services contract complying with §411.354(d)(4) [productivity compensation rules]).
- The geographic area served by the hospital where the physician locates his or her office is the lowest number of contiguous zip codes from which the hospital derives 75% of its inpatients.
- The relocation is at least 25 miles, *or* the new practice derives 75% of its revenues from professional services furnished to patients, including hospital inpatients not seen or treated by the physician at his or her prior location within the 3 preceding years (for the first year, the 75% is satisfied by a reasonable expectation). If the physician is a resident or has been practicing for less than one year, the relocation is not required as long as the physician practices within the geographic area served by the hospital, as calculated above.
- In case of remuneration provided to a physician indirectly through a practice the physician is employed, or directly to a physician who joins a practice, the following additional requirements must be met:
    - The written agreement must also be signed by the practice.
    - Except for the actual costs incurred by the practice in recruiting the physician, the entire remuneration must be paid directly to the physician.
    - If the recruiting arrangement involves an income guarantee, the costs of the practice allocated to or by the physician must not exceed the actual additional incremental costs attributable to the recruited physician.
    - Records of the actual costs passed on to the physician must be kept for 5 years and must be available for inspection.
    - The remuneration from the hospital cannot take into consideration the volume or value of actual or anticipated referrals from either the physician or the practice or any physician affiliated with the practice.
    - The physician or the practice cannot impose practice restrictions on the physician, such as covenants not to compete, other than quality of care requirements.
    - The arrangement must not violate the anti-kickback statute and must comply with relevant claims submission and billing laws.

The Phase II Commentary provides that reasonable hospital credentialing restrictions on physicians becoming competitors are permitted. [195] The Commentary concludes that physician recruiting cannot meet the regulatory "fair market value" exception discussed later in this paper.[196] The Commentary also points out:

> [I]f the physician practice receiving the payments from the hospital is a DHS entity to which the recruited physician will refer (that is, the practice submits claims to Medicare for DHS), any separate or additional financial relationship it has with the recruited physician will have to fit in an exception (for example, the in-office ancillary services exception). [197]

Practice Alert. *Many hospital recruiting agreements do not meet the Phase II Stark requirements, and will have to be modified or terminated within the 120 day phase-in period. Agreements are not "grandfathered."*

Practice Alert*. The Phase II Commentary makes it clear that if there is any intent to use a recruiting agreement to unlawfully reward or induce referrals from the physician's practice whose practice the hospital chose to underwrite, the Anti-kickback Statute would be violated and the exception would not apply. Hospitals financing recruitment through existing practices with which the hospitals have ongoing relationships must be exceptionally careful in this regard.*[198]

[10] Certain Group Practice Arrangements With Hospitals.

The Stark Statute and the Regulations provide an exception for certain arrangements between hospitals and group practices entered into prior to December 19, 1989.[199] This specialized exception is not discussed in this paper.

[11] Payments by Physicians for Items and Services Exception

Under the Stark, a "compensation arrangement" does not include payments made by a physician (i) to a laboratory in exchange for the provision of clinical laboratory services, or (ii) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value when the items or services are not available under another exception. "Services" mean services of any kind and are not limited to services under the Medicare program.[200] The Phase II Regulations extend the rule to payments made by members of a physician's family. [201]

[12] Prepaid Plans

Stark and the Phase I Regulations provide an ownership and compensation exception for certain *prepaid plans*.[202] This exception coordinates with the *risk sharing* regulatory exception, 42 C.F.R. §411.357(n), and is discussed under that exception later in this paper.

[G] Regulatory Exceptions

In addition to the statutory exceptions described above, CMS has promulgated several regulatory exceptions. For the most part, these exceptions add an "intent" requirement not otherwise found in Stark because to be compliant with these exceptions, compliance with the Anti-kickback Statue is required.

[1] Academic Medical Centers

The Phase I Regulations provided a regulatory ownership and compensation exception for academic centers.[203] Phase II Regulations liberalized and expanded this exception, and now permit hospitals with four or more teaching programs to qualify for this exemption as an "accredited academic hospital." However, the availability of this exemption to community hospitals is extremely limited, since the exception also requires that a majority of the medical staff at the hospital be faculty members and a majority of the hospital admissions must be made by teaching members of the medical staff.[204] This special exception is not discussed in further detail in this paper.

[2] Implants at ASC

Phase I Regulations established an ownership and compensation exception for implants by an ASC as a DHS facility.[205] The exception was felt necessary because many implants are not billable in the ASC bundled rate. The exception applies only to an ASC and only when the ASC, not the physician, bills for the services.[206] To meet the exception, the implants (as defined in the Regulations) must meet the following conditions:

- The implant must be provided by the referring physician or a member of his or her group practice in a Medicare-certified ASC with which the physician has a financial relationship.
- The implant procedure must be paid by Medicare to the ASC as a procedure under 42 C.F.R. § 416.65.
- The arrangement must not violate the anti-kickback laws.
- All billings and claims submission must not violate federal or state law or regulations.

[3] Fair Market Value Compensation Exception

The Phase I Regulations adopted the fair market value compensation exception proposed under the 1998 Proposed Stark Regulations.[207] No changes were made in this exception under the Phase II Regulations.

However, the Phase II Regulations made substantial changes in the definition of fair market value and provide hourly rate safe harbors, discussed earlier in this paper. The Phase II Commentary also creates uncertainty by indicating that although a range of methods for the determination of fair market value may be available, a "good faith" determination based on a particular valuation method will not establish the ultimate issue of the accuracy of the fair market valuation.[208]

This exception is a "catch-all" for various types of compensation arrangements that might not fit squarely within one of the other compensation arrangement exceptions. The exception applies to compensation resulting from an arrangement between an entity and a physician (or immediate family member) or any group of physicians (regardless of

whether the group meets the definition of a group practice) if the arrangement is set forth in an agreement that meets all of the following conditions:

- The arrangement is expressed in a signed written agreement that covers only identifiable items or services, all of which are specified in the agreement.
- The agreement specifies the timeframe for the arrangement, which can be for any time. The arrangement may also contain a termination clause, if the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than one 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.
- The agreement specifies the compensation payable under the arrangement. The compensation must be "set in advance," must be consistent with fair market value, and must not be determined in a manner that takes into account the volume or value of any referrals or any other business generated between the parties.
- The agreement involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties.
- The agreement meets a safe harbor under the Anti-Kickback Statute, has been approved by the OIG under a favorable advisory opinion, or otherwise does not violate the Anti-kickback Statute.
- The services to be performed do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

With the addition of the requirement that the use of this exception not violate the Anti-kickback Statute (and other exceptions that similarly reference this law), the exception will require a determination of the *intent* of the physician and the entity in entering into the compensation arrangement. Under Stark statutory exceptions unmodified by Regulations, intent is not relevant.

The addition of the requirement that the arrangement also not involve the counseling or promotion of a business that violates *any* state or federal law also raises uncertainty. Apparently, this provision is unrelated to the intent of the parties, or with substantial compliance with other laws. For example, in Florida, referrals are governed by the Florida Patient Self-Referral Act of 1992, as amended. That law is also fraught with uncertainty.

This exception does not apply to items or a service provided by a physician and is available even though other exceptions may also be available.[209]

[4] Non-Monetary Compensation up to $300 and $25 Medical Staff Benefits Exceptions

The Regulations adopt a $300 annual *non-monetary compensation* exception and, separately, a $25 per item *medical staff incidental benefit* compensation exception.[210]

Non-monetary compensation paid to a physician in the form of items or services is exempt under the compensation exception when the value of the items and services

provided any physician does not exceed $300 per year, provided the compensation is not solicited by the physician and the compensation does not take into consideration the volume or value of referrals or other business generated by the physician.[211]

The Phase I Commentary makes it clear that the non-monetary compensation must be paid directly to the physician and not to his or her group practice. For example, if a hospital provided a $3,000 computer to a ten-physician group practice, the gift would not qualify for the exception even though the "per physician" amount of the gift was $300.[212]

The medical staff incidental benefit must meet the following requirements:

- The compensation must be provided to all members of the medical staff within the same specialty without regard to the volume or value of referrals or other business generated, even if all members do not accept it.
- Except for listing as medical staff on a hospital website, or in hospital advertising, the compensation is provided only during periods the physician is making rounds or engaged in activities benefiting the hospital.
- The compensation is provided by the hospital and used by the medical staff member on the hospital's campus. Compensation in the form of pagers, internet access, and two-way radios used off campus may only be used for access to medical records or information or patient or personnel access for persons who are on campus.
- The compensation is reasonably related to the provision of, or designated to facilitate, delivery of medical services on the hospital campus.
- The compensation is $25 or less with respect to each occurrence of the benefit. [213]

The Phase II Commentary and Regulations indicate the $300 and $25 amounts will be indexed for inflation annually.[214]

The Phase II Commentary make the observation that a computer provided by a hospital that is wholly dedicated to use related to hospital services benefits the hospital and is not remuneration under Stark. The Phase II Commentary also state that dictation services provided to a physician by a hospital for the dictation of hospital patient records are not compensatory; however, dictation services provided for the dictation of the physician's patient records are compensatory.[215]

The Phase II Commentary also illuminates when meals provided by a hospital in connection with attendance at hospital or medical staff board meetings and hospital sponsored CME qualify for the medical staff incidental benefits exception. A special additional regulatory exception has also been provided for referral services. The Commentary also clarifies that the medical staff incidental benefit exception is not limited to hospitals, but also applies to other *bona fide* medical staffs.[216]

The Phase I Commentary notes that the medical staff incidental benefits exception would not permit a hospital to provide malpractice insurance benefits for physicians, since the

payment of the premiums would be related to the provision of emergency services at the hospital.[217]

The 1998 Proposed Stark Regulations Commentary states that the non-monetary expense exception covers non-cash items or services, such as "gift certificates, stocks or bonds or airline frequent flyer miles."[218]

Although state law is beyond the scope of this paper, state laws should also be considered when considering gifts. For example, Florida's Patient Brokering Statute provides that the payment of an ordinary and necessary business expense that is tax deductible is not a kickback and does not violate this criminal law.[219] Making a gift to a health care provider in excess of the amount allowed under the non-monetary exception could violate this state law since the gift would not be tax-deductible.

[5] Risk Sharing Arrangements

The *risk sharing arrangements* compensation exception applies to compensation between a managed care organization, IPA and a physician, directly and through subcontractors, for services provided to plan enrollees when the compensation does not violate the Anti-kickback Statute.[220]

[6] Compliance Training

The *compliance training* compensation exception authorizes DHS entities to provide compliance training to physicians within their local areas.[221] Compliance training does not include CME (which may be permitted under the $300 non-monetary exception), but does include training regarding federal, state and local laws governing physician conduct as well federal health care plan requirements, policies, procedures, staff training, internal monitoring and reporting. The training must be held in the local area.

[7] Anti-kickback Safe Harbors

Although CMS refused to adopt all of the Anti-kickback Statute Safe Harbors, it did adopt two special compensation exceptions, *referral services* and *obstetrical malpractice insurance subsidies.*[222] Each of these exceptions must meet all of the provisions contained in the applicable Safe Harbor.

[8] Professional Courtesy

Professional courtesy may be provided under a compensation exception by a DHS entity to a physician or a physician's immediate family or office staff when all of these conditions are met:

- Professional courtesy is offered to all physicians on the entity's medical staff or in the local community or service area without regard to volume or value of referrals or other business generated.

- The health care items and services are of the type routinely offered by the entity.
- The professional courtesy is set out in writing and approved in advance by the entity's governing body.
- The professional courtesy is not offered to a physician or family member who is a beneficiary of a federal health care program without a good faith showing of need.
- If the professional courtesy involves the whole or partial reduction of a coinsurance obligation, the insurer is informed in writing.
- The arrangement does not violate the Anti-kickback Statute, or any federal or state law or regulation governing claims and billing.[223]

[9] Charitable Donations

A *bona fide charitable donation* by a physician or immediate family member is a compensation exception when the donation:

- Is made to a tax-exempt organization under the Internal Revenue Code.
- Is neither solicited, nor made, in a manner that takes into account the volume or value of referrals or other business generated.
- Does not otherwise violate the Anti-kickback Statute, or federal or state laws regulating claims and billing.[224]

The Phase II Commentary points out that broad-based solicitation of charitable funds not targeted specifically at physicians meet this exception. Selective or targeted solicitation must be structured to assure that the solicitation does not take into account referrals.[225]

[10] Preventative Screening, Immunization, and Vaccines

The *preventative screening* services exception is both a compensation exception and an ownership exception.[226] This exception covers certain screening tests, immunizations, and vaccines which are reimbursed by Medicare and identified by CPT/HCPCS codes. The tests are subject to CMS-mandated frequency limits. The tests also must not violate the Anti-kickback Statute or federal or state laws related to billing and claims. Diagnostic services, such as Pap tests, are not protected by this exception.

[11] Eye Glasses and Contact Lenses Following Cataract Surgery.

The *eye glasses and contact lenses following cataract surgery* exception is both a compensation and ownership exception.[227] The glasses or lenses must be provided in accordance with Medicare coverage and payment policies, and the arrangement must not violate the Anti-kickback Statute or federal or state law about claims and billing.

[12] Intra-family Rural Referrals.

The *intra-family rural referrals* exception is both a compensation and ownership exception.[228] A referral by a physician to a member of his or her immediate family or to

an entity furnishing DHS with which family member has a financial relationship is excepted from the referral prohibition if:

- The patient resides in a rural area;
- No person is available to furnish the patient services in a timely manner in light of the patient's condition within 25 miles of the patient's residence;
- For patients who receive services where they live (such as home health services), there is no other person available to furnish the services in a timely manner in light of the patient's condition; and
- The financial relationship does not violate the Anti-kickback Statute or federal or state laws about billing and claims.

To fall under this exception, the physician must make reasonable inquiries as to the availability of persons or entities within a 25 mile radius of the patient's residence. Reasonable inquiries include researching telephone directories, professional associations, other providers or internet resources. A decision by a physician that other services are available, but do not meet the physician's standards of quality will not make this exception available.[229]

[13] EPO and Other Dialysis-Related Drugs Furnished in or by ESRD Facility

The *EPO and other dialysis-related drugs* exception is both a compensation and ownership exception.[230] The drugs covered by this exception are included in CMS' list of CPT/HCPCS codes. The exemption applies when the drugs are administered by a physician in an ESRD facility or are dispensed from the ESRD facility for home use. The arrangement must not violate the Anti-kickback laws or federal or state laws about billing and claims.[231]

[14] Retention Payments in Underserved Areas

The *retention payments in underserved areas* exception is a compensation exception.[232] This regulatory exception was adopted to assist hospitals in rural and inner city areas. The exception is limited to a HPSA area, regardless of whether the HPSA is specifically designated for the physician's specialty. The Phase II Commentary indicates that retention agreements outside a HPSA will be considered on a case-by-case basis through advisory opinions.[233] To qualify for the exception:

- The compensation payment must be provided by a hospital or a federally qualified health center to retain a physician in the entity's service area.
- The provisions of §§411.357(e)(1)(i) though (iv) must be satisfied (these are provisions of the recruiting agreement exception).
- The geographic area is a HPSA, regardless of the physician's specialty.
- The physician has a *bona fide* offer from another, unrelated hospital or federally qualified health center making payment, and the offer specifies the payment and would require the physician to move at least 25 miles *and* outside the geographic area of the hospital or qualified health center.

- The retention payment is limited to the lower of (i) the amount determined by subtracting the physician's current income from the amount the physician would receive in the *bona fide* offer to move (calculating the amounts under reasonably similar and consistent methodology over a period not to exceed 24 months), or (ii) the reasonable costs the hospital or qualified center would have to spend to recruit a replacement physician.
- The retention payment is subject to the same obligations and restrictions, if any, on payment and forgiveness as in the *bona fide* offer.
- The hospital or qualified center does not enter into a retention agreement with a physician more frequently than once every 5 years.
- The retention agreement is not altered during the term of the agreement to take into consideration the volume or value of referrals or other business generated.
- The arrangement does not violate the Anti-kickback Statute, or federal or state law related to billing and claims.

The Phase II Regulations permit CMS to waive the relocation requirement through the advisory opinion process for demonstrated need.

[15] Community-wide Health Information Systems

The *community-wide health information systems* exception is a compensation exception.[234] The exception authorizes items or services of information technology provided to a physician by a DHS entity that enable the physician to participate in a community-wide health information system when:

- The items or services are designed to allow physician access or sharing of electronic health records, complementary drug information, general health information, medical alerts and related information for patients served by the community providers.
- The items or services are:
    - Available as necessary to enable participation.
    - Principally used by the physician as part of the community-wide health system.
    - Not provided to the physician in any manner that takes into consideration the volume or value of referrals or other business generated.
- The health information system is available to all providers, practitioners and residents of the community who desire to participate.
- The arrangement does not violate the Anti-kickback Statute or other federal or state laws about billings and claims.[235]

[16] Indirect Compensation Arrangements

We discuss the *indirect compensation arrangements* exception in our discussion of compensation, section [D][2] and financial relationships, section [C][3]. Because of the complexity involving indirect financial relationships and the application of the indirect compensation exception against the necessity to keep records about financial

relationships and report them on request from CMS or the OIG, we include this further discussion. We discuss reporting requirements in section [G].

The Regulation[236] provides that indirect compensation meets this Stark exception when:

- The compensation received by the referring physician or immediate family member described in § 411.354(c)(2)(ii) [the indirect compensation provision] is fair market value for services or items actually provided and is not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician with the DHS entity.
- The compensation arrangement described in § 411.354(c)(2)(ii) [the indirect compensation provision] is in writing, signed by the parties and specifies the services covered by the arrangement, except in the case of a *bona fide* employment arrangement between an employer and employee, in which case the arrangement need not be in writing, but must be for identifiable services and must be commercially reasonable even if no referrals were made to the employer.
- The compensation arrangement does not violate the Anti-kickback Statute or federal or state laws about claims and billings.

The Phase II Commentary makes it clear that indirect compensation determined under § 411.354(c)(2)(ii) includes time-based and unit-of-service based compensation.[237] However, *if* the indirect compensation is fair market value, compensation that meets the time-based or unit-based tests provided in §§411.354(d)(2) and(3) will be considered as satisfying the indirect compensation exception. The Commentary also points out that fixed indirect compensation that is excessive and reflects referrals would not meet the test.

Indirect ownership interests are not protected by the indirect compensation exception. [238] Indirect compensation arrangements that meet the "time-based" or "unit-based" tests in §411.354(d) are deemed not to vary with the value or volume of referrals or amount of business generated between the parties, to meet the requirements of this exception. The compensation arrangement does not also have to meet the "set in advance" requirements of §411.254(d)(1) to meet the indirect compensation exception. [239]

The following are examples from the Commentary illustrating indirect compensation arrangement issues:

- Physician A owns an interest in a hospital. The hospital contracts for DHS services with a clinical laboratory to which the physician also refers. The clinical laboratory and the physician are deemed to have an unbroken chain of financial relationships through the physician's hospital ownership. Under these circumstances, to determine whether or not there is an indirect compensation arrangement, we look to the non-ownership or non-investment interest closest to the referring physician in the unbroken chain. That relationship is between the hospital and the laboratory. Since the laboratory, the DHS entity, does not pay the hospital compensation, the hospital does not receive "aggregate compensation"

based upon referrals or business done; therefore, there is no indirect compensation. However, if the laboratory charged the hospital less than fair market value, indirect compensation would be present. [240]

- Physician A is an inventor and is paid royalties by a medical device company related to a device implanted during surgery performed by the physician. (Medical devices are not DHS.) The hospital where the physician performs the surgery buys the devices and is reimbursed under Medicare. Although the devices are not DHS, the physician has an indirect compensation arrangement with the hospital, since he is referring the hospital inpatient services, which are DHS. If the royalty arrangement is fair market value, the indirect compensation exception is met (as long as it meets the requirements of unit-based compensation and does not vary over the term of the arrangement, as provided in §411.354(d)). [241]
- A physician is co-owner with a hospital that leases MRI equipment from the co-owned entity. The lease arrangement creates an indirect compensation arrangement between the physician and the hospital because the co-owned entity receives lease payments that are based upon a "per click" arrangement. However, if the per click arrangement is fair market value, and does not vary over the term of the agreement, the requirements of §411.354(d) would be satisfied and the indirect compensation exception would be met. [242]

[17] Certain Arrangement Involving Temporary Non-Compliance

The exception for *certain arrangements involving temporary non-compliance* is intended to provide relief from the mandatory compliance requirements of the Stark Statute and Regulations for arrangements that have temporarily fallen out of compliance after periods of full compliance.[243]

This exception will not help physicians and other DHS entities that have never been in "complete" compliance. Thus, this exception cannot be used to extend the 120 day period before the Phase II Regulations become effective.

For this exception to apply:

- The arrangement must have complied with Stark for not less than 180 calendar days preceding the date of noncompliance.
- The DHS entity that is not in compliance must have fallen out of compliance for reasons beyond the entity's control and the entity must take steps to rectify its noncompliance.
- The DHS entity has otherwise complied with the Anti-kickback Statute and other applicable laws and regulations applying to billing and claims.
- The period of noncompliance cannot exceed 90 days.

The exception does not apply to the $300 non-monetary exception or to incidental medical staff benefits. The Phase II Commentary indicates the purpose of the exception is for a DHS entity to collect late signatures on documents and provide for changes in classification of rural areas and conversions of public companies to private companies,

and similar circumstances. The Commentary recommends that a DHS entity relying on this exception document the noncompliance and steps taken to rectify compliance issues. The exception may only be used once every three years by the same referring physician.[244]

[H] Reporting Requirements

The Phase II Regulations include a new regulation related to physician and other DHS entity reporting requirements at 42 C.F.R. § 411.361. Under this regulation all entities furnishing services for which payment is made under Medicare must submit information to CMS or to the OIG concerning their "reportable financial relationships" in the form, manner and at times specified.

The reporting requirement does not apply to entities furnishing less than 20 Part A or Part B services in a calendar year. Thus, its application is essentially universal. The information to be furnished *upon request* will include:

- The name and UPIN of each physician who has a reportable financial relationship with the entity.
- The name and UPIN of each physician's family member who has a reportable financial relationship with the entity.
- The covered service furnished by the entity.
- With respect to the reported physician, the nature of the financial relationship in the detail specified in the Regulation and the request.

A "reportable financial relationship" is any ownership or investment interest defined in §411.354(b) or any compensation arrangement defined in §411.354(c), except for investments in publicly-traded securities and mutual funds. The information must be provided within 30 days following a request. The information submitted is subject to pubic disclosure. Failure to comply with the request subjects the DHS entity to fines of up to $10,000 each day.

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 # vStark Handbook version with plus

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[4] 66 Fed. Reg. 856 (2001).

[5] 69 Fed. Reg. 16054 (2004).

[6] *See* 42 U.S.C. § 1395nn(g) (2004).

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[13] *See* 63 Fed. Reg. 1659, 1712 (1998).

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[29] 42 C.F.R. § 411.354 (2004).

[30] 42 C.F.R. § 411.354(b)(5) (2004).

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[52] 42 C.F.R. § 411.351 (2004).

[53] 42 U.S.C. 1395nn (2004); 42 C.F.R. § 411.351 (2004).

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[105] 66 Fed. Reg. 878 (2001); 69 Fed. Reg. 16087 (2004); 42 C.F.R. § 411.354(d)(4) (2004).

[106] 69 Fed. Reg. 16070 (2004).

[107] 69 Fed. Reg. 16098 (2004); 42 C.F.R. § 411.351 and § 411.357(f)(2004).

[108] 42 U.S.C. § 1395nn(h)(4) (2004).

[109] 42 U.S.C. § 1399nn(h)(4)(B)(i) (2004).

[110] 42 C.F.R. § 411.352 (2004).

[111] 42 C.F.R.§ 411.352(a) (2004).

[112] 69 Fed. Reg. 16076 (2004).

[113] 42 U.S.C. § 411.352 (2004).

[114] 69 Fed. Reg. 16077 (2004).

[115] 69 Fed. Reg. 16076 (2004); 42 C.F.R. §§ 411.351-2 (2004).

[116] 42 C.F.R. § 411.352(c) (2004).

[117] 42 C.F.R. § 411.352(d) (2004).

[118] 69 Fed. Reg. 16070 (2004).

[119] 42 C.F.R. § 411.352(d)(5) (2004).

[120] 42 C.F.R. § 411.352(d)(6) (2004). The Regulations refer to § 411.457, but it is a typo.

[121] 42 C.F.R. § 411.352(h) (2004).

[122] 69 Fed. Reg. 16076 (2004).

[123] 69 Fed. Reg. 16080 (2004).

[124] 66 Fed. Reg. 907 (2001).

[125] 42 C.F.R. § 411.352(i) (2004).

[126] 69 Fed. Reg. 16080 (2004).

[127] 42 C.F.R. § 411.352(i)(2) (2004).

[128] 42 C.F.R. § 411.352(i)(3) (2004).

[129] 66 Fed. Reg. 909 (2001).

[130] *See* Medicare Carrier's Manual § 2050.1(A) (2001).

[131] 66 Fed. Reg. 909 (2001).

[132] 42 U.S. C. § 1395nn(h)(4)(B)(i) (2004).

[133] 42 C.F.R. §411.352(i) (2004).

[134] 63 Fed. Reg. 1659, 1690 (1998).

[135] 42 C.F. R. § 411.352(e) (2004).

[136] 42 U.S.C. § 1395nn(b)(1) (2004); 42 C.F.R. § 411.355(a) (2004).

[137] 69 Fed. Reg. 16070 (2004).

[138] 42 C.F.R. § 411.355 (a)(2) (2004).

[139] 66 Fed. Reg. 879 (2001); *see* 42 C.F.R. § 411.355(a) (2004).

[140] 42 U.S.C. § 1395nn(b)(2) (2004); 42 C.F.R. § 411.355(b) (2004).

[141] 42 C.F.R. § 411.355(b) (2004).

[142] 69 Fed. Reg. 16073 (2004).

[143] 69 Fed. Reg. 16073 (2004).

[144] 69 Fed. Reg. 16074 (2004).

[145] 42 C.F.R. § 411.355(c)(4) (2004).

[146] 69 Fed. Reg. 16070 (2004).

[147] 42 C.F.R § 411.355(b)(5) (2004).

[148] 69 Fed. Reg. 16072 (2004).

[149] 42 C.F.R. § 411.351 (2004).

[150] 42 C.F.R. § 411.355(b)(6) (2004).

[151] 69 Fed. Reg. 16074 (2004).

[152] 42 C.F.R. § 411.351 (2004).

[153] 42 C.F.R. § 411.351 (2004).

[154] 66 Fed. Reg. 893 (2001).

[155] 63 Fed. Reg. 1696 (1998).

[156] 66 Fed. Reg. 902 (2001).

[157] 42 U.S.C. § 1395nn(c) (2004); 42 C.F.R. § 411.356(a) (2004).

[158] 69 Fed. Reg. 16081 (2004).

[159] 69 Fed. Reg. 16081 (2004).

[160] 42 C.F.R. §411.356 (c)(2004).

[161] 69 Fed. Reg. 16084 (2004).

[162] 42 C.F.R. § 411.355(i) (2004).

[163] 69 Fed. Reg. 16083 (2004); 42 C.F.R. § 411.355(j) (2004).

[164] 69 Fed. Reg. 16083 (2004).

[165] 42 U.S.C. §1395nn(e)(2) (2004); 42 C.F.R. § 411.357(c) (2004).

[166] 69 Fed. Reg. 16087 (2004).

[167] 69 Fed. Reg. 16088 (2004).

[168] 69 Fed. Reg. 16088 (2004).

[169] 42 U.S.C. § 1395nn(e)(1)(A)(B) (2004).

[170] 42 C.F.R. § 411.357(a) and (b) (2004).

[171] *See* 63 Fed. Reg. 1659, 1714 (1998).

[172] 42 C.F.R. §§ 411.357(a)(2) and (b)(3) (2004).

[173] 69 Fed. Reg. 16086 (2004).

[174] 69 Fed. Reg. 16085 (2004).

[175] 69 Fed. Reg. 16086 (2004).

[176] 69 Fed. Reg. 16085 (2004); 42 C.F.R. § 411.352(d) (2004).

[177] *See discussion* under the Fair Market Value section of this paper; *see also* 69 Fed. Reg. 16085 (2004).

[178] 42 U.S.C. § 1395nn(e)(3)(A) (2004); 42 C.F.R. § 411.357(d) (2004).

[179] 42 C.F.R. § 411.351 (2004). The term and its conditions are defined in § 1877(e)(3)(B)(ii) of the Social Security Act.; *see also* the discussion at 69 Fed. Reg. 16089 (2004) and the regulation, 42 C.F.R. § 411.357(d)(2) (2004).

[180] 42 C.F.R. § 411.357(d)(1)(iv) (2004).

[181] 69 Fed. Reg. 16090 (2004).

[182] 42 C.F.R. § 411.357(d)(1)(ii) (2004).

[183] 69 Fed. Reg. 16090 (2004).

[184] 69 Fed. Reg. 16092 (2004).

[185] 42 U.S.C. § 1395nn(e)(6) (2004).

[186] *See* 63 Fed. Reg. 1659, 1669 (1998).

[187] 42 C.F.R. § 411.357(f) (2004).

[188] 42 C.F.R. § 411.351 (2004).

[189] 69 Fed. Reg. 16098 (2004).

[190] 69 Fed. Reg. 16092 (2004).

[191] 42 U.S.C. § 1395nn(e)(4) (2004); 42 C.F.R. § 411.357(g) (2004).

[192] 69 Fed. Reg. 16093 (2004).

[193] 69 Fed. Reg. 16094 (2004).

[194] 42 U.S.C. § 1395nn(e)(5) (2004); 42 U.S.C. § 411.357(e) (2004). The Regulations apply this exception to any federally qualified health center.

[195] 69 Fed. Reg. 16095 (2004).

[196] 69 Fed. Reg. 16096 (2004).

[197] 69 Fed. Reg. 16097 (2004).

[198] 69 Fed. Reg. 16097 (2004).

[199] 42 U.S.C. § 1395nn(e)(7)(2004); 42 C.F.R. § 411.357(h) (2004).

[200] 42 U.S.C. § 1395nn(e)(8) (2004); 42 C.F.R. § 411.357(i) (2004).

[201] 69 Fed. Reg. 16099 (2004).

[202] 42 U.S.C. § 1395nn(b)(3) (2004); 42 C.F.R. § 411.355(c) (2004).

[203] 42 C.F.R. § 411.355(e).

[204] 69 Fed. Reg. 16108 (2004).

[205] 42 C.F.R. § 411.355(f) (2004).

[206] 69 Fed. Reg. 16111 (2004).

[207] 42 C.F.R. § 411.357(l) (2004).

[208] 69 Fed. Reg. 16107 (2004).

[209] 66 Fed. Reg. 917 (2001).

[210] 42 C.F.R. §§ 411.357(k) and 357 (m)(2004).

[211] 42 C.F.R. § 411.357(k) (2004).

[212] 66 Fed. Reg. 920, 921 (2001).

[213] 42 C.F.R. § 411.357(m) (2004).

[214] 69 Fed. Reg. 16112 (2004).

[215] 69 Fed. Reg. 16113 (2004).

[216] 69 Fed. Reg. 16114 (2004).

[217] 66 Fed. Reg. 921 (2001).

[218] 63 Fed. Reg. 1659, 1699 (1998).

[219] FLA. STAT. ANN. § 456.054(1) (2004).

[220] 42 C.F.R. § 411.357(m) (2004).

[221] 42. C.F.R. § 411.357(o) (2004).

[222] The applicable "safe harbors" are found at 42 C.F.R. §1001.952(f) and (o); the Stark exceptions at 42 C.F.R §§411.357(q) and (r) (2004).

[223] 42 C.F.R. § 411.357(o) (2004).

[224] 42 C.F.R. § 411.357(j) (2004).

[225] 69 Fed. Reg. 16116 (2004).

[226] 42 C.F.R. § 411.355(h) (2004).

[227] 42 C.F.R. § 411.355(i) (2004).

[228] 42 C.F.R. § 411.355(j) (2004).

[229] 69 Fed. Reg. 16082 (2004).

[230] 42 C.F.R. § 411.355 (g) (2004).

[231] 69 Fed. Reg. 16117 (2004).

[232] 42 C.F.R. § 411.357(t) (2004).

[233] 69 Fed. Reg. 16097 (2004).

[234] 42 C.F.R. § 411.357(t) (2004).

[235] 69 Fed. Reg. 16113 (2004).

[236] 42 C.F.R. § 411.357(p) (2004).

[237] 69 Fed. Reg. 16059 (2004).

[238] 69 Fed. Reg. 16061 (2004).

[239] 69 Fed. Reg. 16061 (2004).

[240] 69 Fed. Reg. 16060 (2004).

[241] 69 Fed. Reg. 16060 (2004).

[242] 69 Fed. Reg. 16061 (2004).

[243] 42 C.F.R. § 411.353(f) (2004).

[244] 69 Fed. Reg. 16057 (2004).