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STARK II FINAL RULE – SUMMARY AND ANALYSIS[1/]

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I. INTRODUCTION

On January 4, 2001, the Department of Health and Human Services ("HHS") Health Care Financing Administration ("HCFA") released the long-awaited final regulation (the "Final Rule") for the physician self-referral statute known as the "Stark Law." The Final Rule, which comes with a 90-day comment period, represents the first of two "Phases" to be issued by HCFA. The Final Rule gives as its effective date one year from publication, January 4, 2002, except for one section relating to physician referrals to home health agencies, which is effective February 5, 2001, but this date may be affected by President George W. Bush's order to postpone by 60 days published rules not yet in effect.

We note that even a brief reading of this Summary and Analysis will make it abundantly clear the complicated nature of the Stark Law and Final Rule. This Summary and Analysis is intended to aid providers and their counsel in obtaining a preliminary overview of the issues raised in the Stark Law and this Final Rule, but nothing should be construed as providing legal advice.

A. Background of the Stark Law

The Stark Law, section 1877 of the Social Security Act ("Act") (42 U.S.C. § 1395nn), was enacted by Congress in response to a number of studies that demonstrated that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships. To prevent the resulting overutilization of services, the Stark Law prohibits a physician from referring a Medicare or Medicaid patient to an entity for certain designated health services if the physician (or an immediate family member) has a financial relationship with the entity unless the financial relationship falls completely within one of several exceptions.[2] Financial relationships are generally classified as either an ownership or investment interest or compensation arrangements.

In general, the Stark Law creates *per se* ownership prohibitions if an ownership exception is not met, but compensation arrangements are regulated through highly prescriptive compensation exceptions. As a result of this approach, although the Stark Law is often referred to as a referral prohibition, it more accurately regulates self-referrals.

As originally written in 1989, the Stark Law restricted a physician from referring a patient to an entity for clinical laboratory services for which Medicare might pay if the physician had a financial relationship with the entity ("Stark I"). The statute was later amended in 1993 to expand the referral restrictions to additional "designated health services" ("DHS") and to extend aspects of the Medicare restrictions on physician referrals to Medicaid.

Where there is a financial arrangement not permitted by an exception, the statute prohibits the referral itself for a DHS, and also prohibits the entity receiving the referral from presenting or causing to be presented a Medicare claim or bill to any individual, third party payer, or other entity for the DHS. Payment for the service would be denied in the event that such a claim or bill is submitted, and the entity receiving the payment must refund any payment already received. Finally, the statute imposes certain reporting requirements and provides for sanctions, including civil monetary penalties, for failure to comply.

B. Differences from the Federal Anti-Kickback Statute

The Stark Law differs from and is independent of the Federal Anti-Kickback Statute, section 1128B(b) of the Act (42 U.S.C. § 1320a-7b(b)), which prohibits the knowing and willful offering, paying, soliciting or receiving remuneration of any type in return for or to induce the referral of business reimbursable by Medicare or Medicaid. While the Federal Anti-Kickback Statute requires wrongful intent for a violation of its provisions, the Stark Law does not. No

[2] For brevity, we will not further discuss the impact on physicians' immediate family members.

wrongful intent or culpable conduct is required for a violation of the Stark Law, and the remedy for a referral made in violation of the statute is the denial of payment for the item or service rendered, without penalties. If payment has already been made, the remedy is recoupment of the overpayment by the Medicare program, again without penalties. By contrast, the Federal Anti-Kickback Statute is a criminal statute, the violation of which is punishable by fines, imprisonment, or both. In addition, the Stark Law only applies to physician referrals, but the Federal Anti-Kickback Statute applies to all referral sources and prohibits other conduct, such as the arranging for or recommending items, services or facilities.

The Final Rule reflects the continuing confusion in the relationship between the two statutes. At first blush it would appear that the Stark Law should be, in HHS's words, a "minimum threshold" for Medicare payment purposes whereby certain financial arrangements may be permitted under the Stark Law but could still run afoul of the criminal provisions Federal Anti-Kickback Statute. Although that is indeed the case in many situations, there are also many instances where there are arrangements that do not comply with the Stark Law, perhaps for minor technical reasons, but would not be found illegal under the Federal Anti-Kickback Statute, in most cases because there is no criminal intent. Complicating these analytical difficulties, HHS continues its ambivalence in whether to link the two statutes or keep them separate. Although HHS states that the two statutes are separate, and compliance with the Stark Law does not confer protection related to other statutes, in many parts of the regulation HHS makes compliance with the Federal Anti-Kickback Statute a condition to Stark Law compliance. Of course, the requirement that an arrangement comply with the Federal Anti-Kickback Statute is made at the direct sacrifice of clear, bright-line rules because the determination of compliance with this law requires an examination of the intent of the parties.

C. <u>HHS's Approach to Drafting the Final Rule</u>

HHS has clearly attempted to extensively reexamine the statutory language and legislative history, carefully reconsider the January 1998 Proposed Rule, and closely review the industry concerns about the Proposed Rule and Stark Law itself. HHS stated that it wants to avoid the "unintended disruption" of common financial arrangements, yet not adversely impact the delivery of services to Medicare beneficiaries. HHS also stated that it intended where possible to issue clear "bright-line" rules as this standard was the goal specifically claimed by its principal sponsor, Rep. Fortney ("Pete") Stark (D.Cal.) in 1988 when he first introduced the bill that eventually came to be known by his name. Toward these goals, HHS tried to interpret the prohibitions narrowly and the exceptions broadly, focusing on financial relationships that may result in overutilization. By interpreting the Stark Law in this manner, HHS interpreted the reach of the Stark Law as narrowly as possible consistent with the statutory language and congressional intent.

Of note, although not publicly acknowledged, it is our understanding that the Office of Inspector General ("OIG") provided substantial technical assistance to HCFA in the drafting of the Final Rule. This assistance is clear as the Final Rule contains many footprints of OIG policies and enforcement concerns. Because of the OIG's role with HCFA and the official clearance of the Final Rule by the Secretary, we refer to the Final Rule as being drafted by HHS even though HCFA is officially responsible for the Final Rule and enforcement of the Stark Law.

D. Phase I and Phase II

HHS issued the Final Rule in two parts: Phase I implements a majority of the provisions of the Stark Law, certain exceptions, and related definitions, as applied to the Medicare program. The principal portions of the Stark Law that are deferred to Phase II are the reporting requirements, the sanctions provisions, and the application of the Stark Law to the Medicaid program. In addition, Phase II will also incorporate comments received about Phase I. Although HHS states formally in the preamble that it is deferring implementation of a final rule regarding the well-known statutory ownership and compensation exceptions contained in subsections (c), (d) and (e) of section 1877 (for example, employee and personal services exceptions), the mechanics of the rule itself give the appearance that the existing regulations applicable to Stark I and clinical laboratory services that implement these ownership and compensation provisions have been left intact and therefore arguably are incorporated into the Stark II Final Rule and will become applicable for all DHS.

HHS promises that Phase II will be issued "shortly." This promised time-frame must be understood in context. Stark I was enacted in 1989 with a final rule not implemented until 1995. Stark II was enacted in 1993 with an effective date of January 1995, but with the Proposed Rule not issued until January 1998. This Final Rule was issued in January 2001 and only implements Phase I. Thus, few people will be holding their breath awaiting Phase II.

II. HIGHLIGHTS OF THE FINAL RULE

A. Overview

The Final Rule injects a substantial dose of common sense and understanding of the realities of the impact of the Stark Law on the enormously complex health care market. On balance, it appears that HHS took commenters' concerns to heart and has introduced a variety of adjustments and amendments that offer greater clarity and, in several instances, increased protections for legitimate arrangements.

It appears that HHS has taken a strategic straddling position to a statute that some HCFA officials have quietly hoped they would not need to implement because of its complexities and the lack of departmental resources. The combination of issuing the rule in two phases, coupled with the first phase not becoming effective for a full year, and even then without two key enforcement weapons – reporting obligations and sanctions – all make it seem like HHS is offering a trial balloon or beta testing of a liberalized set of rules that have some chance of being palatable to providers and Capitol Hill. Certainly, HHS was looking over its shoulders at the hand-full of attempts by House Committee leaders from both parties to significantly rollback or amend major provisions of the Stark Law. So while this Final Rule contains important provisions that will need to be understood and complied with, the outcome of self-referral enforcement is a long way from being final.

Two competing forces raise questions about the actual effective date of the Stark Law and Final Rule. In a September 29, 2000 letter to Rep. Stark, the Department of Justice

announced that it had over 50 matters under investigation involving possible violations of the Stark Law that were brought by whistleblowers under the *qui tam* provisions of the False Claims Act. Presumably such actions are premised under the theory that Stark II became effective by statute in January 1995. On the other hand, one of President Bush's first actions on January 20th was to issue a memorandum calling for the postponement by 60 days of all published rules not yet in effect. Although the practical and legal effects of this order are not clear, it further clouds an already murky situation. Whatever the various forces within the new administration determine to be the actual effective date, without question whistleblowers and their counsel will continue to bring False Claims Act cases based on the statutory effective date and their view that the Stark Law is clear on its face.

B. Highlights

The Final Rule contains several new provisions or revised interpretations of the Stark Law that we will summarize here with more details below. The Final Rule contains four significant interpretations and/or exceptions, which taken together, provide significant relief and flexibility to providers.

- HHS has introduced a knowledge standard that limits the enforcement of the Stark Law to "knowing" violations as defined in the Final Rule. This will prevent unfair enforcement of the statute where non-compliance with an exception is *de minimus* or unintended. The consequence of this approach is to introduce uncertainty because an examination of intent is now required. Ironically, HHS has determined that Rep. Stark's promise of clear bright-line rules is illusory and ultimately not achievable.

- In addition, in a sweeping new interpretation, HHS has determined that a "referral" does not take place when a physician refers a patient for a service he or she personally performs. This elimination of "pure self-referrals" can apply to services a physician performs in the office or the professional component of a hospital service.

- HHS has introduced a fair market value exception and related definition that generally permits under certain guidelines payments based on a "per use," "per service," "per click," or "per time period" basis, but does not permit many common percentage compensation arrangements because it violates the requirement for payments to be "set in advance." In addition, the requirements for this exception have been significantly liberalized from the Proposed Rule.

- HHS has also defined "indirect compensation arrangements" and created a related exception. The concept of indirect compensation could apply to a large number of arrangements that must be analyzed to determine compliance with the definition and the exception. Along with the fair market value exception, this new compensation exception, despite its unnecessarily complex structure, will provide significant relief, and will likely become the primary compensation exceptions to which providers will turn. These two exceptions will substantially diminish the impact of any Phase II rule with respect to the implementation of the remaining statutory compensation exceptions.

The Final Rule also contains important changes to statutory definitions and exceptions and creates new regulatory exceptions in the following areas:

- Key Statutory terms and definitions of designated health services
- In-Office Ancillary Services
- Managed care
- Academic medical centers
- EPO or other prescription drugs furnished by ESRD facilities
- Non-cash gifts or benefits of minimal value

Key Statutory Terms and Definitions of Designated Health Services.

- A person or entity is generally considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS.

- Unexercised stock options and unsecured loans are not ownership interests.

- "Under arrangement" services provided by physician-owned providers need only comply with the compensation exceptions.

- Under certain rules, a compensation arrangement may be conditioned on referrals.

- Many of the DHS services are clearly defined by CPT or HCPCS codes.

- Included within radiology and other imaging services are the technical and professional component of the service, but excluded are invasive procedures.

- Outpatient prescription drugs includes all such drugs covered under part B.

In-Office Ancillary Services. This exception and the related definition of a group practice are some of the most controversial and complicated parts of the Stark Law. In an effort to ease unnecessary regulatory burdens for physicians, the Final Rule makes significant improvements to the in-office ancillary services exception.

- One of the requirements for qualifying as a group practice is that it must be a "unified business." The Final Rule creates a more flexible requirement that generally permits a group practice to use cost-and location-based accounting with respect to services that are not DHS.

- By statute, group practices may pay certain productivity bonuses and shares of overall profits. The Final Rule provides a listing of qualifying payment methods.

- HHS has expanded the scope of services included in the in-office ancillary services by permitting –
    - outpatient prescription drugs, such as chemotherapy infusion drugs, to be "furnished" in the office, even if the patient takes the drugs at home;
    - external ambulatory infusion pumps that are durable medical equipment ("DME") to be provided under the in-office ancillary services exception; and
    - certain items of DME to be furnished in a physician's office without restricting their ability to mark-up such items.
- The "direct supervision" requirement now conforms to relevant Medicare and Medicaid payment and coverage rules for the specific service. Additionally, the independent contractors may supervise the furnishing of DHS services.
- Shared DHS facilities are allowed as long as the physicians or groups that share the facility routinely provide their full range of services in that same building. In certain cases, part-time practitioners would be permitted to share the DHS facility, as long as they are not providing DHS.

Managed Care. The Final Rule addresses two principal problems created by the very narrow Prepaid Health Plan exception, with HHS's stated goal of avoiding the "unintended disruption" of many physician arrangements with health maintenance organizations ("HMOs") or managed care organizations ("MCOs").

- HHS clarified that typically it is not the network-type HMO, MCO, PSO, or IPA that is the entity actually furnishing the DHS services, but rather it is the provider with whom these entities contract. With this clarification, HHS wanted to make sure that it generally permitted physician ownership of such entities.
- HHS created a new "risk-sharing" exception because the statutory Prepaid Plan exception does not protect physician arrangements involving commercial or employer-provided group plans – typically the so-called commercial product paralleling the Medicare MCO product – that include some Medicare retiree members. Specifically, HHS determined that additional protection was needed to protect managed care incentive compensation, for example, withholds, bonuses and risk pools not protected by either the employment or personal services exceptions.
- Both of these exceptions specify that downstream providers are protected, but so-called "pull through," i.e., referrals of fee-for-service non-plan beneficiaries, is not protected.

Academic Medical Centers. HHS has created a new exception for academic medical centers because of the unique symbiotic relationships involved and because the flow of funds and

referrals within academic medical settings do not easily fit within other exceptions. However, in Stark contrast (sic) to other parts of the Final Rule, this exception is unnecessarily narrow, and hopefully will be revisited based on comments submitted to HHS.

EPO Or Other Prescription Drugs Furnished By ESRD Facilities. As expected, HHS is permitting EPO and other prescription drugs to be furnished by ESRD facilities under certain rules.

Non-Cash Gifts Or Benefits Of Minimal Value. HHS created three new compensation exceptions related to the provision of non-cash gifts or benefits of minimal value to physicians. The three new exceptions are for (i) non-monetary compensation where the value does not exceed $300 per year; (ii) hospital medical staff incidental benefits, such as reduced or free parking, free computer/Internet access and meals; and (iii) compliance training provided by hospitals.

C. Other Guidance

The Final Rule contains useful guidance in a number of areas, both with respect to analysis of issues under the Stark Law and the Federal Anti-Kickback Statute.

- Physicians need not report discounts they receive on drugs provided in their offices.
- Congress did not intend to prohibit physician ownership of dialysis facilities.
- Fair market value guidance –
    - The preamble suggests that the analysis should first look to what the service could have been bought for in the absence of an arrangement with a referring physician. However, in the absence of reasonable market comparables, the fair market analysis can next look at the supplier's costs plus a reasonable return.
    - With respect to the need to obtain an outside appraisal, the preamble suggests that internal valuations are "susceptible to manipulation [and] do not have a strong

- The preamble makes a number of comments regarding arrangements that may either be suspect under the Federal Anti-Kickback Statute or at least need to be analyzed closely for compliance.
    - Per-use or per-service compensation arrangements where the business is derived from referrals by the physician who is to receive the compensation.
    - Hospital "under arrangement" services provided by referring physicians should be examined.

- Valuing ancillary referrals as part of the acquisition price of a physician's practice is suspect.

- Termination clauses in one-year contracts are acceptable.

- Payments for a non-compete where there are no restrictions on referrals are acceptable (presumably if reasonably valued).

III. GENERAL PROHIBITION AND KEY STATUTORY TERMS

The Final Rule amends the existing Stark I regulation applicable to clinical laboratory services, 42 C.F.R. § 411 Subpart J, to the entire list of DHS. While the prohibitions seem relatively straightforward on paper, upon closer examination of key terms, certain nuances become evident. The Final Rule revises and fully develops the key statutory terms "referral," "entity," "financial relationship," "remuneration" and "compensation arrangement." In addition, *scienter* element. In section IV below we discuss separately the statutory DHS terms. In addition, many parts of the Final Rule refer to the requirement that payments be made at "fair market value." Because of the importance of this term and HHS's creation of a "fair market value exception," we discuss those issues separately in section V below.

A. Referral

As in the Proposed Rule, the term "referral" is broadly defined and can be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused, directs or controls the referral made by someone else. A referral can be in any form, including, but not limited to, written, oral or electronic means of communication. A referral can also be made in a plan of care. It does not require the physician to send a patient to a particular entity or to indicate in the plan of care that DHS should be performed by a particular entity.

One of the most significant interpretations in the Final Rule is HHS's determination that the term "referral" excludes services personally performed by the referring physician. (Similarly, HHS revised the definition of "entity" to clarify that the referring physician himself or herself is not an entity for purposes of the statute.) Because there are so many situations where one component of a referral involves a pure self-referral for services personally performed by the referring physician, this interpretation removes a substantial amount of conduct from the ambit of the Stark Law. For example, any personally performed service a physician provides in his or her office or at a hospital is not covered by the Stark Law under this interpretation. Examples of personally performed services at a hospital include the professional component of cardiac catheterization and lithotripsy. For the most part, these services are physician services, although as discussed below the professional component of a radiology service is deemed to be a radiology service. A referral still takes place when a physician refers a patient to another member of his or her group practice or to another entity for a DHS, including the technical component of the radiology service or the hospital service itself.

HHS raises the question regarding referrals within a group practice where the service is performed by an employee of the referring physician. In most cases such referrals will be permitted under the new, substantially broadened, in-office ancillary services exception. Consequently, HCFA notes that it is soliciting comments as to whether, and under what conditions, services performed by a physician's employees could be treated as the physician's personally performed services.

By statute, a referral does not include certain requests, pursuant to a "consultation," by pathologists, radiologists, and radiation oncologists. A consultation is separately defined to mean a request by another physician documented in the patient's medical record follow-up by a written report to the treating physician. HHS clarifies that this term is broader and separate from coverage and payment rules for a consultation.

The Final Rule specifies that a physician's prohibited referral will not generally be imputed to his or her group practice, its members, or its staff. Although HHS attempts to clarify these issues here, it leaves many unanswered questions by virtue of what is not in the rule.

B. Entity

The referral must be to an entity furnishing DHS. The term "entity" is, again, notable for what it does not include. Most of the definition remains unchanged from the Proposed Rule, but an amendment makes clear that an entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is generally considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS, directly, upon assignment on the patient's behalf, or upon reassignment pursuant to HCFA's reassignment rules. The Final Rule also clarifies that neither medical device manufacturers nor drug manufacturers are "entities" for purposes of the Statute because they do not furnish prescription drugs. However, a pharmacy that delivers outpatient prescription drugs directly to patients would be an entity for such purposes. As discussed in section VIII below, this revised definition of "entity" has important ramifications for managed care.

C. Financial Relationship

A "financial relationship" can be through an ownership or investment interest or compensation arrangement. Surprisingly, HHS takes the position that an ownership or investment interest is a subset or type of compensation arrangement. However, a financial arrangement qualifying under an ownership exception need not also qualify under a compensation exception. Both ownership interests and compensation arrangements may be either direct or indirect. With respect to ownership interests, the Final Rule states that generally an ownership interest in a subsidiary is not an ownership interest in the parent or other subsidiaries. Unexercised stock options and unsecured loans are not ownership interests.

D. Remuneration

This term is relevant for compensation arrangements. The Final Rule broadly defines "remuneration" to mean "any payment or other benefit made directly or indirectly, overtly or

covertly, in cash or in kind… ." By statute, this term specifically excludes certain laboratory-related exceptions. These include exceptions for forgiveness of amounts owed on inaccurate or mistakenly performed tests or procedures, and the furnishing of items, devices, supplies used solely to collect, transport, process, or store specimens for the entity furnishing the service.

E. Compensation Arrangement

As discussed above, HHS has changed its interpretation of the term "compensation arrangement" in very important ways, in particular by defining the term "indirect compensation arrangement" and creating a new indirect compensation exception, both of which we discuss separately in section VI below. The regulation clarifies that "under arrangement" services provided by physician-owned providers need only comply with the compensation exceptions.

The Final Rule creates an exception by way of definitionally carving out certain arrangements that are "conditioned" on referrals where the underlying compensation complies with one of the relevant exceptions. To qualify, the payment must be fixed in advance and at fair market value pursuant to a signed written agreement. The required or conditioned referral must be voided if the patient expresses a preference to be treated by another provider, the patient's insurer specifies the provider to which the patient should be referred, or the referral is not in the patient's best medical interest. We note that the regulation itself does not require the physician or facility to make any type of affirmative disclosure to the patient, such as that there is a financial relationship with the physician, that there is an agreement that generally requires, or that a list of alternative providers is available. Given that the fundamental premise of the Stark Law questions the ability of the referring physician to act in the patient's best medical interest where there is a financial relationship, this exception makes evident how extensively HHS has rethought the appropriateness of using the Stark Law to regulate the health care marketplace.

F. Knowledge Standard

HHS recognized the draconian effect of the denial of payment remedy where an unintentional or technical violation of one of the complicated rules, for example involving a minor compensation arrangement with a referring physician, could cause a hospital to repay all of the Medicare revenues related to the admissions of, or services ordered by, that physician for the period of non-compliance. Consequently, in one of the most significant provisions of the Final Rule, HHS has added a *scienter* or knowledge requirement. Payment may be made for a service made pursuant to an otherwise prohibited referral if the entity did not have actual knowledge or act in reckless disregard or deliberate ignorance of the identity of the referring physician. Elsewhere in the Final Rule, similar knowledge standards are imposed that prevents the statute from applying unfairly. This new knowledge element is in sync with the term "knowing" as applied under other federal laws and HHS's Civil Monetary Penalty Law.

This knowledge standard does not generally impose upon providers an affirmative obligation, absent some information that would put a reasonable person "on alert," to inquire as to indirect financial relationships or to investigate whether an indirect financial relationship with a referring physician exists. Instead, providers are required to make "reasonable inquiries" when in possession of facts that could lead a reasonable person to suspect the existence of an indirect

financial relationship. The "reasonable steps" to be taken, the preamble contends, will depend upon the circumstances.

The addition of the knowledge standard will provide welcome relief by preventing the Stark Law from being applied unfairly. Nonetheless, it represents the ultimate repudiation of Rep. Stark's original promise to be able to regulate physician self-referrals throughout the health care landscape through bright-line rules. However alluring such a concept is, HHS appears to have recognized that bright-line rules can bring arbitrary enforcement with significant financial consequences to providers. In contrast, most will agree that HHS's new approach, while sacrificing bright-line rules, preserves the underlying principles of the statute and will achieve more effective enforcement.

IV. DEFINITIONS OF DESIGNATED HEALTH SERVICES

A. Listed Designated Health Services

The Stark Law lists the following Designated Health Services:

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

Because some of these DHS are either relatively straightforward or contain issues of interest to only a small audience, we confine our discussion to only a few of these DHS services.

B. New Approach to Defining Certain DHS

In an effort to reduce confusion regarding which services constitute DHS, HHS took a new approach by defining the entire scope of a number of DHS according to the Current Procedural Terminology ("CPT") and HCFA Common Procedure Coding System ("HCPCS") codes that are commonly associated with those DHS and familiar to the provider community. Now specifically identified by CPT and HCPCS codes in an Attachment to the Final Rule (but not appearing in the Code of Federal Regulations) are clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services, and radiation therapy services. HHS deemed the definitions for the remaining DHS clear enough not to warrant including their CPT or HCPCS codes in the attached list of codes. Any future changes to this list of codes will be reflected in the annual addendum to the Final Rule concerning payment policies under the physician fee schedule rule. Additionally, an updated list will be posted on

HCFA's website (www.hcfa.gov). According to HHS, the published list of codes will be controlling in all cases.

C. Radiology and Certain Other Imaging Services

As discussed above, the categories of radiology and other imaging services and radiation therapy services are defined by listed CPT and HCPCS codes. HHS reiterated that both the professional component and the technical component of any diagnostic test or procedure using x-rays, ultrasound, or other imaging services, computerized axial tomography, or magnetic resonance imaging are considered part of the DHS. However, to resolve confusion created by its use in the proposed rule of the term "invasive radiology procedure," HHS revised its definition of "radiology and certain other imaging services" to exclude x-ray, flouroscopy, and ultrasound services that are themselves invasive procedures that require the insertion of a needle, catheter, tube, or probe, such as cardiac catheterizations and endoscopies. HHS also specifically excluded from this category nuclear medicine services, certain covered preventive screening procedures, such as screening mammography, that are subject to HCFA-imposed frequency limits that mitigate the potential for abuse, and radiology procedures that are integral to the performance of, and performed during, a nonradiology medical procedure.

D. Outpatient Prescription Drugs

Under the Final Rule, all outpatient prescription drugs covered by Medicare Part B, including injectibles, constitute DHS. HHS clarifies that, unless otherwise directed to do so, discounts related to drugs provided by a physician in the physician's office that were acquired at a discount do not need to be passed along to the Medicare program. Also, HHS excepts from DHS erythroprotein ("EPO") and certain other drugs required for dialysis when furnished by an end-stage renal disease ("ESRD") facility with which the referring physician has a financial arrangement. Similarly, certain vaccinations, immunizations and preventive screening tests subject to HCFA-imposed frequency limits are also excepted.

E. Inpatient and Outpatient Hospital Services

Inpatient and outpatient services provided to a hospital patient, whether provided by the hospital or provided under arrangements with another entity, are considered DHS. The Final Rule provides that inpatient and outpatient hospital services provided under arrangement, such as lithotripsy and cardiac catheterization services are specifically included within this DHS category. However, the impact of this determination is substantially diminished by HHS's other determination that professional services personally furnished by the referring physician are not part of a hospital service, or do not otherwise constitute a referral.

V. FAIR MARKET VALUE DEFINITION & EXCEPTION

NOTE: In these next three sections V - VII, we continue our discussion of definitions with three key statutory terms: "fair market value," "indirect compensation arrangement," and

"group practice." However, because these terms are directly related to exceptions, these next three sections combine our discussion of these terms with the exceptions.

A. Fair Market Value Definition

One of the most significant aspects of the fair market value exception is HHS's interpretation of the "volume or value" standard. HHS has finally explicitly embraced the congressional view that payments based on a "per use," "per service," "per click," or "per time period" basis do not take into account the value or volume of referrals so long as the payment per unit is at fair market value at the inception and does not change during the term of the agreement in any manner that takes into account the DHS referrals. This interpretation of the volume or value standard will be applied uniformly throughout the Stark regulations.

HHS's clarification of the "set in advance" requirements is consistent with the "volume or value" standard. As long as the amount of the payment on a "per use," "per service," "per click," or "per time period" basis is established in advance, the aggregate payment need not be specified in advance. It is important to note that HHS does not consider many common percentage compensation arrangements to be "set in advance." These include payments based on a percentage of gross revenues, collections, expenses or multiple fee schedules. However, HHS appears open to receiving comments and reconsidering this issue.

The requirement that the compensation cannot take into account "other business generated between the parties" means that the fixed, fair market value payment cannot take into account, or vary with not only DHS referrals but any other business generated by the referring physician including other Federal and private pay business. In other words, the compensation should be at fair market value for the work performed and not inflated to compensate for the physician's ability to generate other revenues.

The determination of "fair market value" has always been a difficult issue for those trying to fit within any of the Stark exceptions. The statute and existing Stark I regulation define fair market value as arms-length transactions, consistent with the general market value. The Final Rule provides further guidance by defining "general market value" as bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for one another. In addition, although HHS states that it will accept any reasonable method of valuation, it cautions parties to maintain good documentation supporting valuation and frowns on internally generated valuations.

B. Fair Market Value Exception

The new "fair market value compensation" exception created under HHS's statutory authority to create exceptions that do not pose a risk of program abuse should prove very valuable to physicians and entities who seek to set up a business relationship. This exception itself is relatively straightforward, and incorporates the volume or value restrictions discussed above. The exception will protect arrangements where the compensation paid to a physician is, among other things, set in advance, consistent with fair market value and does not take into account the value or volume of referrals or other business generated by the referring physician.

As with other Stark exceptions, the arrangement must involve a transaction that is commercially reasonable. Commercial reasonableness is determined viewing the transaction in the context of the particular business in which the parties are involved.

Many of the constraints parties now face when drafting contracts under Stark have been loosened by the new fair market value compensation exception. For example, the written contracts need not be for a year so long as the parties enter into only one arrangement for the same items or services during the course of the year. An arrangement made for less than one year may be renewed any number of times although the terms and the compensation may not change. Additionally in the Final Rule, HHS drops a particularly burdensome requirement in the proposed fair market value compensation exception that all other arrangements between the parties must be cross-referenced in the agreement.

The fair market value exception requires parties to be sure that the arrangement either meets a safe harbor under the Federal Anti-Kickback Statute, has been approved by the OIG under an advisory opinion, or does not violate the Federal Anti-Kickback Statute. Since none of the safe harbors under the Federal Anti-Kickback Statute permit arrangements for less than one year or permit payments based on a per use or per service basis, for this exception to apply, the arrangement must comply with Federal Anti-Kickback Statute. The bright-lines that HHS has attempted to draw in the Final Rule become somewhat blurred by this requirement. Most arrangements will have to be subject to a full analysis under the Federal Anti-Kickback Statute, particularly the parties' intent, in order to make a determination that the arrangement does not violate the Federal Anti-Kickback Statute.

VI. INDIRECT COMPENSATION DEFINITION AND EXCEPTION

In perhaps one of the more significant new features of the Final Rule, HCFA recognizes that the statute either doesn't reach or doesn't adequately protect indirect compensation arrangements. Therefore, HHS creates a defined term of "indirect compensation," and creates a broad exception under its statutory authority, which HHS states is intended to parallel the fair market value exception.

An example of the type of problem HHS sought to address was its determination that the statutory compensation exceptions, such as employment or personal services, did not protect arrangements between hospitals and physician groups for the provision of services, for example medical director services, by group members who are referring physicians. Because such hospital-physician arrangements are made through an intermediate entity – the physician's group practice – a new category of exception was needed. Despite HHS's claims that this definition and exception involve a "simple" test, it is anything but that. Because so many arrangements are covered by its scope, it will become a very important exception for providers and counsel to understand. Although the definition and exception are unnecessarily complex, and may be difficult to apply to a particular set of facts, many of the concepts are derived from other parts of the regulation, particularly the fair market value exception. As will be seen, one of the principal complicating characteristics of this indirect compensation exception is that HHS uses many of the same concepts, on the one hand, in the definition section in order to bring an arrangement

under the purview of this exception, and on the other hand, in protecting the arrangement in the exception section.

A. Definition of Indirect Compensation

In what it calls a "simple test" to identify whether an indirect compensation relationship exists, HCFA defines "indirect compensation" as containing three elements.

1. Unbroken Chain Test

The first element requires, as between the referring physician and the entity furnishing DHS, that there must exist "an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them." In other words, this first element is met if there is an unbroken chain of any type of financial relationships from the DHS entity to the referring physician, regardless of the form or purpose of the payments or their relationship to the DHS referrals. An example of an indirect compensation arrangement between a hospital and a physician that would meet this test would be a consulting agreement with a practice management subsidiary of a hospital and a physician group for the consulting services of a physician member of the group.

2. Volume or Value Test.

The second element in the definition is the volume or value test. Although the definition of "volume or value" is not new, an understanding of how it is to be applied here requires close reading. HHS seems to be saying that if payments are made based upon the volume or value of referrals, it is an arrangement that must comply with this exception. In applying this test, HHS has departed from its requirement announced in the proposed rule that required providers to trace payments. Instead, the focus of this second element under the Final Rule is the direct financial relationship with the referring physician, i.e., the last financial relationship in the chain. The only exception is where the direct financial arrangement with the referring physician is an ownership or investment interest, in which case the analysis moves up the chain until the first compensation arrangement is found. So in our simple example of medical director services contracted for by a hospital, we first look to the direct financial arrangement with the physician. This is the physician's financial interest in the group practice. Because that relationship is an ownership interest, we move upstream to the hospital's compensation to the group practice. Similarly, in the case of under arrangement services between hospitals and physician-owned service providers, the analysis is of the compensation between the hospital and the service provider. The regulation elsewhere makes clear that physician-owned under arrangement providers do not constitute an ownership interest, but need only comply with a compensation exception.

Once the reference point of the direct financial arrangement is found, the next step in the analysis is whether that compensation arrangement contains aggregate compensation that varies with the volume or value of referrals or business otherwise generated.

3. Knowledge

The third element of indirect compensation adds a similar knowledge element that applies to the overall regulation. For an indirect compensation relationship to exist, the entity furnishing DHS must have knowledge, within the meaning of the regulation, that the referring physician's compensation "varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS." As noted above, the knowledge element does not impose an affirmative duty on providers to investigate. It does, however, require the DHS entity to make a reasonable inquiry into the relationship when it has reason to suspect a financial relationship exists.

B. Exception for Indirect Compensation Arrangements

The icing on the indirect compensation cake is a new exception for certain indirect compensation arrangements. The new exception protects an indirect compensation arrangement if all the following conditions are satisfied: (1) The compensation received by the referring physician (or immediate family member) is fair market value for services and items actually provided not taking into account the value or volume or referrals; (2) the compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer; and (3) the compensation arrangement does not violate the Anti-Kickback Statute or any laws or regulations governing billing or claims submission.

For purposes of the new exception, HHS indicates in the Preamble that in determining whether compensation takes into account the value or volume of referrals by the referring physician for the DHS entity, it will apply the "volume or value of referrals" and "other business generated" tests, which permits time-based or unit-of-service based payments, even when the physician receiving the payment has generated it through a DHS referral. Therefore, "per service" or "per use" compensation arrangements can fit in the new exception so long as the payments are fair market value for the items or services provided (i.e., do not include any additional amount that might be attributable to the volume or value of referrals), and the payments do not vary during the term of the compensation arrangement in any manner that takes into account referrals to the DHS entity.

What is striking and indeed confusing is the drafting approach of definitionally pulling in all arrangements that vary based on the volume or value of referrals or business generated, but then permitting – or "excepting" – such arrangements if they are at fair market value. It would appear likely that drafting brevity would have yielded a more genuinely "simple" test than advertised. Nevertheless, in the final analysis the concept of indirect compensation could apply to a large number of arrangements that must be analyzed to determine compliance with the definition and the exception.

VII. DEFINITION OF GROUP PRACTICE AND IN-OFFICE ANCILLARY SERVICES EXCEPTION

The definition of group practice and In-Office Ancillary Services exception is one of the most complicated parts of the Stark Law. Those provisions will be reviewed in this section.

A. Group Practice Definition

The definition of a Group Practice is relevant for compliance with the In-Office Ancillary Services exception,[3/] whose requirements can be summarized in six categories.

1. Single Legal Entity

The Final Rule broadens the types of arrangements that qualify under the "single legal entity" test to include multi-entity legal structures and structures owned by a single physician. To qualify under the single legal entity requirement, there must be one identifiable legal entity that is a bona fide group practice of two or more physicians. The single legal entity can assume any form recognized by the state in which the entity achieves legal status, including, but not limited to, a corporation (for-profit, professional, or non-profit), a partnership, foundation, faculty practice plan, or limited liability company.

2. Members of the Group

A "member of the group" is any physician who owns or is employed by the group practice, but excludes independent contractors. However, independent contractors may supervise the furnishing of DHS services as "physicians in the group practice," and under such circumstances may receive profit shares and productivity bonuses.

3. The "Full Range of Services" Test

Group practice members must provide substantially the full range of "patient care services." Patient care services include all services a physician performs that address the medical needs of specific patients or patients in general or benefit the group practice.

4. The "Substantially All" Test

The "substantially all" test requires that at least 75 percent of the patient care services of the group practice members must be furnished within the group. HHS has modified the requirements of this standard by permitting groups to adopt various methods for determining compliance. The Final rule establishes criteria for measuring compliance.

A requirement under the current Stark I regulation for group practices to "attest" to compliance with this provision has been eliminated. Instead, the Final Rule merely requires that the supporting documentation verifying compliance with this test must be made available to the secretary upon request.

5. The Unified Business Test

[3/] This definition also applies to the physician services exception, a relatively minor ownership and compensation exception, which we will not further discuss.

The Final Rule creates a more flexible requirement that generally permits a group practice to use cost-and location-based accounting with respect to services that are not DHS. Many forms of cost center and location-based accounting are permitted, provided that the compensation formulae with respect to DHS revenues otherwise meet the requirements of the law.

To meet this test, a group practice must also be organized and operated on a bona fide basis as a single integrated business enterprise with legal and organizational integration. Essential elements are: (1) centralized decision making by a body representative of the practice that maintains effective control over the group's assets and liabilities; (2) consolidated billing, accounting, and financial reporting; and (3) centralized utilization review.

The overhead expenses of, and income from, the group must be distributed in accordance with methods "previously determined." The Final Rule treats the distribution methodology as "previously determined" (or determined in advance) if it is determined prior to receipt of payment for the services giving rise to the overhead expense or producing the income. This approach permits groups to adjust their methodologies prospectively as often as they deem appropriate. A compensation method that directly relates to the volume or value of DHS referrals, or is retroactively adjusted, would violate the statute.

6. Profit Shares and Productivity Bonuses

Member physicians and independent contractors who qualify as "physicians in the group" may be paid productivity bonuses based directly on their personal productivity (this includes "incident to" services). Bonuses may not, however, be based directly on referrals of DHS that are performed by someone else. The Final Rule specifies permissible methods for paying productivity bonuses.

With regard to distributions of profit shares, the statute allows group practice members to receive "shares of the overall profits" of the group as long as those profits are unrelated to the volume or value of referrals. The Final Rule defines "share of the overall profits" as meaning a share of the entire profits of the entire group or any component of the group that consists of at least 5 physicians derived from DHS. The Final Rule specifies permissible methods for distributing overall profits.

Group practices are not required to use these illustrative methods set forth for distribution of productivity and overall profit shares. Other methods are acceptable as long as they are reasonable, objectively verifiable, and indirectly related to referrals.

B. <u>In-Office Ancillary Services Exception</u>

1. Scope of DHS That Can Be In-Office Ancillary Services

Under the Final Rule, services are designated to be "furnished" under the exception (1) in the location where the service is actually performed upon the patient or (2) when an item is

dispensed to a patient in a manner that is sufficient to meet Medicare billing and coverage rules. The DME exception now includes crutches, canes, walkers, and folding manual wheelchairs, as long as they meet certain conditions.

The In-Office Ancillary Services exception now includes an exception for a physician or group practice to furnish blood glucose monitors and a starter set of strips and lancets if the physician or group practice furnishes outpatient diabetes self-management training to patients for whom such monitors are furnished. This change is in addition to the furnishing of external ambulatory infusion pumps (other than pumps that are PEN equipment or supplies) as in-office ancillary services covered by the exception.

2. Direct Supervision

After reexamining the statute's legislative history, HHS has recognized that Congress was never intended to impose a physical presence requirement in the strictest sense. Rather, according to the preamble, Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly "ancillary" to the referring physician's medical practice. Consequently, the "direct supervision" is met under the Final Rule merely by complying with the supervision requirements under applicable Medicare and Medicaid payment or coverage rules for specific services at issue.

The Final Rule recognizes that the supervising physician need not be a formal "member of the group," but merely a physician "in a group practice." Thus, owners of the group practice, employees of the group practice, and independent contractors qualify for this purpose.

3. Building Requirements

In general, an in-office ancillary service must be furnished in either the "same building" where the group practice provides professional services or in a "centralized building" where offsite DHS services are furnished. HHS defines "building" to include a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service.

Due to the easing of the "direct supervision" requirement, HHS inserts a stricter interpretation of the location standards "to ensure an adequate nexus between in-office ancillary DHS and the physician's core medical practice." The more significant revision to the location standard requires that the referring physician (or another physician who is a member of the same group practice) must furnish in the same building substantial physician services unrelated to the furnishing of DHS.

This "same building" location requirement has been liberalized in two ways. One, significantly HHS has backed off its previous position, and is now permitting shared facilities under certain constraints. Two, the space in the building in which the DHS is provided need not be adjacent to the space in which the other services are provided.

With respect to the "centralized building" standard, the space must be used exclusively by the group. In other words, the facility must be wholly owned by the group practice or leased by the group on a full-time basis (24 hours per day, 7 days a week). This precludes shared facilities in these buildings.

4. Billing Requirements

To qualify for this part of the rule, DHS must be billed by one of the following: (1) the physician performing or supervising the service; (2) the group practice of which such physician is a member; (3) with respect to services performed or supervised by the supervising physician, the group practice if such physician is "a physician in the group practice;" or (4) an entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice. For purposes of the billing requirement, "wholly owned" does not include joint ventures between group practices and individual group practice physicians or that include other providers or investors that do not qualify as wholly owned entities. The billing number used for billing must be "assigned to the group," and groups "may have or bill under more than one billing number, subject to any applicable Medicare program restrictions." Finally, specific permissible rules are provided for groups to use third party billing companies.

VIII. MANAGED CARE PREPAID PLANS AND RISK-SHARING EXCEPTIONS

In its analysis of the statutory Prepaid Plan ownership and compensation exception, HHS was faced with two principal problems in trying to avoid the "unintended disruption" of many physician arrangements with health maintenance organizations ("HMOs") or managed care organizations ("MCOs"). One, HHS wanted to make sure that it generally permitted physician ownership of network-type HMOs or MCOs, provider-sponsored organizations ("PSOs"), and independent practice associations ("IPAs"). Two, the statutory Prepaid Plan exception does not protect physician arrangements involving commercial or employer-provided group plans – typically the so-called commercial product paralleling the Medicare MCO product – that include some Medicare retiree members. HHS resolved the first major problem by more clearly defining the party that is furnishing DHS. HHS resolved the second major problem by creating a new compensation risk-sharing exception.

As with other parts of the Final Rule, HHS is deferring its treatment of Medicaid managed care plans until Phase II.

A. <u>The Prepaid Plan Exception</u>

The Prepaid Plan exception protects ownership and compensation arrangements for: "services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the [designated] prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization)." The specifically protected prepaid health plans are unchanged from the current Stark I regulation, including for example certain Medicare +Choice Plans, health care prepayment plans, demonstration project MCOs, and Public Health Service Act qualifying HMOs.

In its definition of the term "entity" the Final Rule clarifies that the entity that will be deemed to be furnishing DHS as a general matter is not the HMO, MCO, PSO, IPA, etc., under contract with other entities that directly furnish DHS. Rather, a person or entity is considered to be furnishing DHS if it is the person or entity to which Medicare payment is made for the DHS, directly or upon assignment on the patient's behalf. Thus, a prepaid health plan, or an MCO, PSO or IPA with which the health plan contracts directly or indirectly for services to plan enrollees, will only be considered to be furnishing DHS: (1) when the health plan, MCO, PSO, or IPA furnishes the services directly through an employee or otherwise is the entity to which Medicare payment is made for the DHS directly, upon assignment on the patient's behalf, or pursuant to a valid reassignment under Medicare reassignment rules; or (2) for services provided by a supplier when the health plan, MCO, PSO, or IPA employs the supplier or operates a facility that could accept reassignment from the supplier under Medicare reassignment rules. HHS believes that this change makes it possible for physicians to hold an ownership interest in most types of network IPAs and MCOs, as most do not provide DHS directly, but rather contract with others for the delivery of services to enrollees. However, in the limited situations where the prepaid plan will be deemed to be the DHS provider, HCFA noted that physicians with an ownership interest in the prepaid plan would be prohibited from referring patients to that entity for DHS absent an applicable exception.

The Final Rule makes clear that this exception protects providers, suppliers, and other entities – the "downstream providers" – that provide DHS to enrollees of the protected Medicare prepaid plans under contracts with them, either directly or indirectly. Thus, a physician may refer a patient for DHS covered by the protected Medicare prepaid plans to a MCO that has a Medicare managed care contract or to any entity, provider, or supplier furnishing the services under a contract or subcontract with the MCO. As noted above, this exception and the explicit language of the regulation only protect services furnished "to enrollees" of one of the protected prepaid plans. It does not, however, protect "pull through" patients, i.e., other Medicare beneficiaries served by that prepaid plan or provider pursuant to a commercial product.

B. New Risk-Sharing Compensation Exception

Because there are so many commercial or employer-provided MCO arrangements that serve Medicare beneficiaries, HHS determined that additional protection was needed to protect managed care incentive compensation, for example, withholds, bonuses and risk pools not protected by either the employment or personal services exceptions. Therefore, the Final Rule creates a new risk-sharing compensation exception, which excepts compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan.

While HHS defines the term "health plan" in the same manner as the Federal Anti-Kickback Statute safe harbor, the Final Rule text does not define the term "risk-sharing," and the Preamble makes clear that this term is specifically intended to be broader than the same term used in the Federal Anti-Kickback Statute risk-sharing safe harbors (sections 1001.952(t) and (u)). The arrangement, however, may not violate the Federal Anti-Kickback Statute or any

law or regulation governing billing or the submission of claims, and, as with the Prepaid Health Plan exception, pull through of non-enrollees, i.e., traditional Medicare fee-for-service patients, is not protected.

IX. OTHER EXCEPTIONS RELATED TO BOTH OWNERSHIP AND COMPENSATION

Because the Stark Law is intended to cover those specific services that Congress determined are or could be subject to abuse, HHS has created limited exceptions for those few services or circumstances for which the agency, as required by law, has determined poses a limited risk of abuse and is necessary to promote continuous patient care. These ownership and compensation exceptions are in addition to the statutory exceptions discussed above for In-Office Ancillary Services and Prepaid Health Plans. The exceptions that HHS created here include:

- Clinical Laboratory Services Furnished by ASC, ESRD Facility Or Hospice
- Academic Medical Centers
- Prosthetic Devices Implanted In An Ambulatory Surgical Center
- EPO Or Other Prescription Drugs Furnished In Or By an ESRD Facility
- Preventive Screening Tests, Vaccinations and Immunizations
- Eyeglasses And Contact Lenses Following Cataract Surgery

Our discussion will be limited to the exceptions for academic medical centers and EPO or other prescription drugs furnished in or by and ESRD facility.

A. Academic Medical Centers

Under certain conditions, referred services provided by an academic medical center are excepted from the prohibition under the Stark Law. HHS has created a new exception for academic medical centers because of the unique symbiotic relationship among faculty, medical centers, and teaching institutions and the educational and research roles of faculty and because the flow of funds and referrals within academic medical settings do not easily fit within other exceptions.

In order for the academic medical center exception to apply, the referring physician must be a full-time or substantial part-time employee of the academic medical center, have a faculty appointment at the affiliated medical school and provide substantial academic or clinical teaching services for which he or she is compensated under his or her employment relationship. This exception is not intended to cover physicians providing only occasional teaching services and who are more appropriately considered community physicians. As with the other exceptions, all payments to physicians must be at fair market value and not based in any way on referrals. This exception does not prevent, however, productivity bonuses based on services physicians personally perform.

HHS intends for this exception to apply to "genuine" academic medical settings. Accordingly, the exception requires that all transfers of money between components of the

academic medical center directly or indirectly support the missions of teaching, indigent care, research, or community service. Furthermore, there must be a *bona fide* affiliation between the medical center components as evidenced by a written agreement.

While HHS may have intended for this new exception to provide some relief for academic medical center arrangements that did not quite fit within other Stark exceptions, this new exception is limited in its scope and does not address many legitimate arrangements. For example, it only covers employed physicians at teaching hospitals, medical schools, faculty practice plans, or departmental professional corporations, but does not appear to protect affiliated group practices or physician-hospital organizations with clinical faculty – by far the more common arrangement between physicians and academic medical centers. In addition, reflecting the increased concerns over fraud and abuse in clinical and sponsored research, any monies given to a referring physician for research must be used *solely* to support bona fide research.

B. <u>EPO Or Other Prescription Drugs Furnished In Or By an ESRD Facility</u>

HHS created this exception in part because of its determination there is no quantifiable risk of fraud or abuse due to the strict utilization and coverage criteria for EPO furnished as part of ESRD services. Significantly, HHS determined that Congress did not intend to prevent physician ownership of ESRD facilities. Any physician investments in a home dialysis supply company or other entity that supplies EPO to ESRD facilities or patients pursuant to a contractual relationship with an ESRD facility do not fall under this exception. In other words, physicians may not have an ownership interest in any dialysis facility subsidiary furnishing these services unless an ownership exception is met.

X. OTHER NEW COMPENSATION EXCEPTIONS

HHS also created three new compensation exceptions in addition to those previously discussed above related to fair market value, risk-sharing, and indirect compensation. Responding to concerns that even the provision of a non-cash gift or benefit of minimal value to physicians or their families by an entity to which such physicians refer (referral recipients) could create a compensation arrangement that would bar such referrals, the Final Rule establishes three exceptions to the compensation arrangement referral ban for qualifying gifts and benefits that the rule's drafters believe will not lead to overutilization.

A. <u>Non-Monetary Compensation</u>

The first of these three exceptions applies to gifts or benefits provided by a referral recipient to a physician. To comply, the gift or benefit must not (i) be in cash or a cash equivalent; (ii) exceed $300 in value in any year; (iii) be determined so as to take into account the volume or value of referrals or other business generated by the referring physician; (iv) be solicited by the physician or his practice; and (v) violate the Federal Anti-Kickback Statute.

B. <u>Medical Staff Incidental Benefits</u>

This second exception applies to incidental benefits other than cash or cash equivalents provided by a hospital to a member of its medical staff. The types of benefits that might fall within this exception include reduced or free parking, free computer/Internet access and meals. In general, this exception requires that the benefits must be used on the hospital's campus, and offered to all medical staff members without regard to the volume or value of referrals. In addition, the benefits must be offered only during the periods when the staff members are making rounds or performing other hospital or patient-related duties, and reasonably related to the hospital's medical services. The benefits must also be consistent with the benefits offered to medical staff members by hospitals in the local region, and not exceed $25.00 per occurrence. The HHS does not believe that medical transcription services, which are commonly provided by hospitals, are of nominal value. Finally, as with many other exceptions, the compensation arrangement must not violate the Federal Anti-Kickback Statute.

C. Compliance Training

The third exception is very narrow and applies to compliance training provided by a hospital to a referring physician who practices in the community, and requires that such training must either cover the basic elements of a compliance program or the specific rules of a federal health care program. Thus, a qualifying general training program can focus on training related policies and procedures, training of staff, internal monitoring and reporting, while a qualifying specific program should focus on such requirements, for example, as billing, coding, medical necessity and unlawful referral arrangements.

It is surprising that such a narrow exception would be issued that barely gives lip-service to the OIG's stated encouragement for voluntary compliance. As important as hospital compliance training is, it is hard to understand why the department would only formally recognize compliance programs by this part of the health care community. This rule is also unnecessarily narrow in that it only protects compliance training activities, but it does not appear to protect assistance to physicians in the many other components of a compliance program about which the OIG has gone on record as being necessary elements for an effective compliance program, including, for example, the creation of policies and self-audits.