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HEALTH CARE FINANCING ADMINISTRATION ISSUES PHASE I OF THE FINAL STARK II RULE

See sections on special issues:

- 1 The Self-Referral Prohibition and the Final Rule – An Overview*
- 2 Key Terms Defined in the Final Rule*
- 9 In-Office Ancillary Services Exception*
- 17 Physician Services Exception*
- 18 Permissible Compensation Methodologies Under the Final Rule*
- 22 New Exceptions*
- 26 Exceptions Relating to Managed Care Arrangements*

On January 4, 2001, HCFA published a Stark Law rule (the “Final Rule”) that constitutes the first phase of what will be a two-phase final Stark Law rule. The Health Care Financing Administration (HCFA) states that it intends to publish the second phase shortly. Perhaps due to the two-phase structure of the Final Rule, HCFA also took the unexpected step of making almost all of the Final Rule effective January 4, 2002, an entire year after its publication. (A provision reconciling a separate home health self-referral rule with the Stark Law is effective February 5, 2001.) Notably, the Final Rule was published with a 90-day comment period, ending April 4, 2001. As of the date of this *Health Law Update*, it is not entirely clear how the Final Rule will be affected by the Bush Administration’s memo dated January 20, 2001, which temporarily postpones for 60 days the effective date of regulations that have been published in the Federal Register but have not taken effect.

The Self-Referral Prohibition and the Final Rule—An Overview

Unless an exception applies, Section 1877 of the Social Security Act, commonly referred to as the “Stark Law,” prohibits a physician from making a referral to an entity for the furnishing of designated health services (DHSs) covered by Medicare if the physician or an immediate family member has a financial relationship with the entity. In addition, no entity may submit a claim to Medicare or bill any individual or entity for services furnished pursuant to a prohibited referral, and no payment may be made by the Medicare program for such services. Finally, the Stark Law requires entities that furnish Medicare-covered designated health services to submit reports on their financial relationships with physicians.

Any person that submits a bill or claim for a service the person knows or should know is prohibited by the Stark Law or fails to promptly refund any amounts collected is subject to a civil

monetary penalty of up to \$15,000 per service and could be excluded from

participation in the Medicare program. Failure to meet reporting requirements can result in a civil monetary penalty of up to \$10,000 per day. Violations of the Stark Law may also result in liability under other laws. The Department of Justice recently reported that it was pursuing a substantial number of cases under the civil False Claims Act predicated on violations of the Stark Law.

The notion of a “financial relationship” under the Stark Law is subject to numerous exceptions. Some of the exceptions apply to both ownership and compensation arrangements. Other exceptions apply only to either ownership or investment arrangements.

The Final Rule addresses three sections of the Stark Law: (i) the general prohibition on physician self-referrals and associated claims; (ii) the statutory exceptions that apply to both ownership and compensation arrangements; and (iii) the definitions of key terms, including the definition of a “group practice” and the definitions for each of the 11 DHSs. The Final Rule also addresses new regulatory compensation exceptions promulgated by HCFA under its statutory authority to issue new exceptions to the Stark Law. This leaves several important sections of the Stark Law for “Phase II” of the Stark Law rule, including the statutory ownership and compensation exceptions, reporting requirements, sanctions and expansion to Medicaid. The statutory exceptions yet to be addressed include exceptions for employment, personal services, leases hospital ownership and physician recruitment.

As discussed below, the Final Rule includes some important differences from the proposed rule published in January 1998. In some cases, those changes provide additional clarity and flexibility. In others, the changes have

provided additional restrictions on the scope of permissible financial arrangements.

Key Terms Defined in the Final Rule

In the Final Rule, HCFA clarifies and makes certain important changes to its proposed definitions of the Stark Law’s key terms. Each term is discussed below.

Referral. With certain key exceptions discussed below, the Final Rule defines “referral” broadly, effectively including within the definition any indication by a physician, in any form, that he or she believes the service is necessary. Thus, any request for, order of, certification or recertification of the need for or establishment of a plan of care that includes a DHS is a “referral” unless an exception applies.

Indirect Referrals. The Stark Law only prohibits referrals “to an entity.” Thus, a physician that orders or prescribes a DHS for a patient that may be obtained at any number of entities has not referred the patient “to an entity” unless the physician suggests to or informs the patient that the service can be obtained at a particular entity. However, a physician cannot evade responsibility for a referral by making the referral indirectly through others directed or controlled by the physician. For example, the referrals of a nurse practitioner (NP) and physician assistant (PA) are imputed to the physician(s) who direct or control their referrals, even if the NP and PA make the referrals independently. Further, if a physician makes a referral to or requests a consultation with a specialist and knows or has reason to suspect that the specialist will refer the patient for a DHS to an entity with which the PCP has a financial relationship, the

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specialist's referral for the DHS will be imputed to the PCP. Similarly, if a physician makes a referral to an entity for a DHS and the physician knows or has reason to suspect that the entity will forward the patient to a vendor owned by the referring physician, the referral to the vendor will be deemed to have been made by the physician.

HCFA's notion of indirect referrals in the proposed rule raised concerns that entities furnishing DHSs would be denied payment and would possibly be subjected to recoupment actions for DHSs rendered pursuant to referrals so indirect that the billing entity could not know or have reason to suspect that the referral came from a physician with which the entity has a financial relationship. Consequently, HCFA provides in the Final Rule that Medicare payment may be made pursuant to an otherwise prohibited referral if the entity does not know or have reason to suspect the identity of the physician who made the referral for the DHS and the claim otherwise complies with federal law.

Personally Performed DHSs. HCFA took the position in the proposed rule that physicians make referrals to an "entity" even when the referring physician initiates and personally performs or provides the DHS. In the Final Rule, HCFA abandons this position and excludes from the definition of "referral" a referral for a DHS personally performed or provided by the referring physician. As discussed below, this exception allows entities furnishing DHSs to give employed or contracted referring physicians productivity credit for personally performed DHSs (e.g., echocardiography reads).

Specialist Exceptions. Finally, the Final Rule clarifies the statutory exception from the definition of "referral" for referrals by certain specialists pursuant to consultations.

Specifically, the Final Rule excepts requests by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a radiologist for diagnostic radiology services and a radiation oncologist for radiation therapy if (i) the request for the service results from a consultation requested by another physician from the physician consultant or the physician consultant's group practice and (ii) the tests or services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist. "Consultation" is defined broadly in the Final Rule to include even an extended course of radiation treatments ordered by a radiation oncologist, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Entity. In the proposed rule, HCFA advanced the interpretation that when one entity arranges for and bills for the DHS and another entity actually furnishes the service, both entities have "furnished" the service for purposes of the Stark Law. In response to comments, HCFA changed its interpretation in the Final Rule. The entity "furnishing" the DHS is now limited to the person or entity that HCFA pays for the service, either upon assignment or pursuant to a permitted reassignment. However, a health plan or downstream managed care organization that accepts reassignment is not considered the entity "furnishing" the DHS unless the entity employs the supplier or operates a facility that could accept reassignment from the supplier furnishing the DHS.

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This change has significant implications for physician ownership in lithotripsy and certain other companies that invest in sophisticated and expensive medical technology. Due to Medicare coverage rules, these companies have no choice but to furnish their services “under arrangements” with hospitals, which makes the services a DHS (inpatient or outpatient hospital service). Because the hospital is the billing entity in these arrangements, physicians can now invest in these companies without the investment creating an ownership interest in the entity “furnishing” the DHS. However, as discussed below, such arrangements create an indirect compensation arrangement for which an exception is required.

HCFA rejected arguments that the Stark Law was not intended to apply to the professional component of DHSs. The Final Rule expressly includes in the definition of each DHS any applicable professional component.

Designated Health Services and Service Carve-Outs. The Final Rule defines DHSs as clinical laboratory services; physical therapy, occupational therapy and speech-language pathology services (PT/OT/SLP); radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies (DME); parenteral and enteral nutrients, equipment and supplies (PEN); prosthetics, orthotics and prosthetic devices and supplies (POS); home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

In the Final Rule, HCFA has made two significant and helpful changes in its proposed approach to DHSs. First, a DHS that is a component part of a bundled service paid at a composite rate (e.g., lab included in ASC payment rate) is excluded from the definition of DHS. Second, four DHSs (clinical laboratory, PL/OT/SLP, radiology and radiation therapy services and supplies) are now defined by reference to a list of CPT and HCPCS codes attached to the Final Rule, which will be posted on HCFA’s website and updated at least annually

as part of HCFA’s physician fee schedule rulemaking. While defining these DHSs by reference to a list of codes will provide bright line guidance to the health care industry, the fact that the list is subject to annual updates introduces a new uncertainty into the definition of these DHSs.

Notably, HCFA rejected arguments that the Stark Law was not intended to apply to the professional component of DHSs. The Final Rule expressly includes in the definition of each DHS any applicable professional component.

Additional significant changes to the proposed definitions of DHSs and new service carve-outs are discussed below.

Radiology Services. The Final Rule modifies the definition of “radiology services,” expressly excluding all x-ray, fluoroscopy and ultrasonic procedures that involve the insertion of a needle, catheter, tube or probe through the skin or into a body orifice. Thus, diagnostic angiography, an invasive radiology procedure commonly performed in cardiac cath labs, is clearly excluded from the definition of “radiology services,” as are endoscopy procedures. Nuclear medicine (but not radiation therapy) and radiology procedures that are integral to and performed during nonradiological medical procedures are also expressly excluded from the definition. While the CPT code for bone densitometry (DEXA) scans has been left off the list of included radiology procedures, the code is not on the list of excluded preventative screening tests. Thus, the status of DEXA scans is not completely clear. Notably, the codes for echocardiography and vascular ultrasound procedures are expressly included in the definition of radiology services.

The implications of these changes for clinical joint ventures are significant. For example, the new definition of radiology services clears the way for cardiac cath lab and GI lab ventures, and makes it easier to develop diagnostic cardiology ventures. However, the status of new diagnostic imaging technologies, such as electron beam computerized scans (ultrafast CT or heart scans), for which there is not a specific CPT code are uncertain. The mere absence of a CPT code for these new technologies may not reflect a deliberate decision by HCFA to exclude them from the definition of radiology, but rather, may simply reflect the lack of a national coverage policy for them. Consequently, individuals and entities considering investment in such ventures should obtain additional clarification from HCFA before going forward.

Radiation Therapy and Supplies.

The definition of radiation therapy and supplies is based on the statutory definition, which includes the use of radioactive isotopes. Although nuclear medicine also involves the use of radioactive isotopes, HCFA finds that nuclear medicine services are not generally regarded as radiation therapy. Thus, HCFA has excluded codes for nuclear medicine from the list of CPT/HCPCS codes that define radiation therapy and supplies.

PT/OT/SLP. Responding to complaints that the proposed definition of PT was too broad, HCFA excludes codes for electromyography tests, nerve blocks and arthrocentesis from the list of codes defining PT/OT/SLP.

Outpatient Prescription Drugs.

HCFA changed the definition of “outpatient prescription drugs” in the proposed rule to all prescription drugs covered by Medicare Part B, without regard to whether the drugs are administered by a health care professional or are capable of self-administration. Further, HCFA

dropped its proposed requirement that physicians pass on to Medicare discounts they receive on drugs.

EPO and Dialysis-Related Drugs.

HCFA does not believe that Congress intended for the Stark Law to prevent physician ownership in ESRD facilities. Although the DHSs that are a component part of a bundled service like ESRD services, which are paid through a composite rate, are excepted from the definition of DHSs, the Final Rule recognizes that erythropoietin (EPO) and certain other dialysis-related drugs furnished in or by an ESRD facility are not included in the composite rate and, therefore, could implicate the Stark Law. Thus, the Final Rule includes an exception for EPO and certain dialysis-related drugs listed in the attachment to the Final Rule that are administered or dispensed in or by an ESRD facility. However, this exception does not apply if the drugs are furnished under an arrangement with a manufacturer, distributor or other supplier of the drugs that violates the anti-kickback provisions of section 1128B(b) of the Social Security Act (“anti-kickback statute”).

DME/POS. The Final Rule defines DME with reference to the statutory and regulatory definition of DME for purposes of Medicare coverage. POS is defined as all HCPCS codes for POS covered by Medicare. Responding to complaints that it is difficult to distinguish DME, prosthetics, prosthetic devices and orthotics, HCFA recommends reliance on the DME/POS fee schedule, which categorizes items by HCPCS code and whether the item is DME, prosthetics, prosthetic devices or orthotics.

Implants and Eyeglass/Contacts Incident to Cataract Surgery.

Providing further protection for physician investment in ASCs, the Final Rule includes an exception for referrals for implanted prosthetics,

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prosthetic devices and DME furnished by the referring physician (or a member of the referring physician's group practice) in the same Medicare-certified ASC where the implant is implanted. The Final Rule also includes an exception for eyeglasses and contact lenses furnished incident to cataract surgery regardless of where the items are furnished. However, these exceptions do not apply if the items are furnished under an arrangement with a manufacturer, distributor or other supplier of the items that violates the anti-kickback statute.

Preventative Screening Tests, Immunizations and Vaccines.

Recognizing that certain preventative medical procedures paid under a fee schedule and subject to frequency limitations pose no risk of overutilization, HCFA has created an exception for certain screening tests, immunizations and vaccines listed by CPT and HCPCS codes.

Home Health Services. The Final Rule defines "home health services" by reference to the statutory and regulatory definitions of home health services for purposes of Medicare coverage. HCFA also amends its current regulations to reconcile a separate provision of the Medicare law regulating the financial interests of physicians in home health agencies with the Stark Law. The \$25,000 cap on compensation to referring physicians under that law will no longer apply; however, any financial relationship between a referring physician and a home health agency will need to satisfy an exception to the Stark Law.

Financial Relationship. The Stark Law defines a "financial relationship" as an ownership or investment interest or a compensation arrangement. Each

type of financial relationship is discussed below.

Ownership or Investment Interest. An ownership or investment interest (ownership interest) may be through debt, equity or other means, and includes stock, partnership shares, limited liability company memberships, and loans, bonds or other financial instruments. The Final Rule codifies HCFA's view that only debt that is secured by property or revenue gives rise to an ownership interest. In a significant change to the proposed rule, the Final Rule treats unexercised stock options and unconverted warrants as compensation rather than ownership interests and clarifies that an interest in a retirement plan adopted by an entity does not create an ownership interest in the entity. The Final Rule also codifies HCFA's position that an ownership interest that satisfies an exception to the Stark Law applicable to ownership interests need not also meet a compensation exception for any *bona fide* profit distributions, dividends or interest payments on secured loans.

An ownership interest includes an ownership interest in an entity that holds an ownership interest in any entity that furnishes DHSs. Thus, a referring physician's ownership interest in a parent entity results in an ownership interest in any subsidiary of the parent entity that furnishes a DHS. However, HCFA states that an ownership interest in a subsidiary does not create an ownership interest in the parent or other subsidiaries, although, as discussed in more detail below, an ownership interest in a subsidiary can be part of an indirect compensation arrangement with the parent or another subsidiary.

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Indirect Ownership or Investment

Interest. The Final Rule provides that an indirect ownership interest exists if between the referring physician (or immediate family member) and an entity furnishing DHSs there exists an unbroken chain of persons or entities with ownership or investment interests between them, and the entity furnishing DHSs knows or has reason to suspect that the unbroken chain exists. This definition suggests that a physician and an entity that are co-owners of an entity would have an indirect ownership interest in each other by virtue of such co-ownership.

However, based on the overall structure of the Final Rule and HCFA's concept of indirect compensation arrangements, this broad definition of indirect ownership interest appears to apply only to the analysis of indirect compensation arrangements. In any other context, co-ownership would not appear to create an indirect ownership interest.

Indirect Compensation Arrangement.

In the Final Rule, HCFA discards its proposed concept of indirect compensation as any compensation between the entity furnishing DHSs and a referring physician (or immediate family member) no matter how many levels the compensation passes through and changes in form that it may take. Instead, HCFA establishes a three-part definition of indirect compensation. First, there must exist between the entity furnishing DHS and the referring physician (or immediate family member) an unbroken chain of persons or entities that have financial relationships between them. The language used by HCFA suggests that it does not matter in which direction the ownership interest or compensation arrangement runs, only that each link in the chain has an ownership or investment interest or a compensation arrangement with the next link in the chain. Second, the

aggregate compensation received by the referring physician (or immediate family member) from the person or entity first up the chain must vary with or reflect the volume or value of the physician's referrals or other business generated for the entity furnishing DHSs. (If the referring physician's (or immediate family member's) first financial relationship up the chain is one of ownership or investment, the compensation paid to the first person or entity up the chain to receive compensation is treated as compensation to the referring physician or immediate family member.) Third, the entity furnishing DHSs must have actual knowledge or act in reckless disregard or deliberate ignorance of the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with or reflects the volume or value of referrals or other business generated for the entity furnishing DHSs.

This definition of indirect compensation arrangement is significantly narrower than that in the proposed rule, particularly when the corresponding indirect compensation arrangement exception is considered. Only if the aggregate compensation received by the referring physician (or immediate family member) varies with or reflects the volume or value of the physician's referrals to the entity furnishing DHS can an indirect compensation arrangement even exist. Moreover, an indirect compensation arrangement does not exist unless the entity furnishing DHSs knows about it or has reason to suspect that it exists. Only if the entity has information that would lead a reasonable person to suspect the existence of an indirect compensation arrangement is the entity required to take reasonable steps to determine whether such an arrangement exists, and, if so, whether it qualifies for the new indirect compensation exception.

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Indirect Compensation Exception.

Further limiting the impact of HCFA's definition of indirect compensation arrangement is the Final Rule's new broad exception for such arrangements. Indirect compensation arrangements do not create a prohibited financial relationship if (i) the aggregate compensation received by the referring physician (or the first person or entity up the chain from the referring physician with a direct compensation arrangement) is fair market value for the services actually provided (not taking into account the value or value of referrals or other business generated by the referring physician for the entity furnishing DHSs); (ii) the physician's compensation is set forth in a signed writing specifying the services covered by the arrangement (except in the case of employment, in which case the arrangement need only be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and (iii) the arrangement complies with the anti-kickback statute and Medicare billing rules.

Does the indirect compensation exception permit compensation on a percentage basis? There is no express requirement in the exception that compensation be "set in advance." However, HCFA's discussion of the "volume or value" standard creates the possibility that in order for compensation not to take into account the volume or value of referrals or other business generated between the parties, the aggregate compensation or per service or per use payment must be fixed in advance. Additionally, if indirect compensation need not be set in advance, the "set in advance" requirement in the personal services and fair market value compensation arrangement exceptions could be easily avoided by interposing another legal entity into the arrangement.

Compensation Arrangement Analysis.

The following hypothetical illustrates how indirect financial relationships will be analyzed under the Final Rule. Hospital X contracts with an orthopedic group to read x-rays taken of inpatients, bills the x-rays on a global basis and pays the group on a per read basis. The group enters into a written contract with Physician A, an orthopedic specialist, to read the x-rays on behalf of the group. Physician A makes a valid reassignment to Hospital X of her right to payment from Medicare for reading the x-rays. The group compensates Physician A on a per read basis for the fair market value of reading the x-rays. Physician A refers patients to Hospital X, some of whom require x-rays that are read by Physician A pursuant to Hospital X's arrangement with the orthopedic group. Consequently, the aggregate compensation paid to Physician A by the group varies with the volume and value of the Physician A's referrals to Hospital X. The hospital knows that such a variable compensation arrangement exists; however, neither Hospital X or Physician A intend to offer, solicit, pay or receive remuneration to induce or in return for referrals covered by a federal health care program.

Based on these facts, an indirect compensation arrangement exists between the Physician A and the hospital. First, the arrangement consists of an unbroken chain of persons or entities with financial relationships with each other (Physician A has a compensation arrangement with the group, and the group has a compensation arrangement with the Hospital X). Second, the aggregate compensation received by the Physician A varies with the volume of referrals generated by the physician for Hospital X, a provider of DHSs. Finally, Hospital X knows that Physician A's aggregate compensation varies with the volume

and value of her referrals to Hospital X.

However, this compensation arrangement qualifies for the new indirect compensation arrangement exception because (i) the per read compensation received by Physician A is fair market value for the services actually provided; (ii) Physician A's compensation is set forth in a signed writing specifying the x-ray interpretation services covered by the arrangement; and (iii) Hospital X and Physician A lack the requisite intent for a violation of the anti-kickback statute and Physician A's reassignment to Hospital X satisfies Medicare reassignment rules, so the arrangement complies with the anti-kickback statute and Medicare billing and claims rules.

Immediate Family Member. A prohibited "financial relationship" can be with a referring physician or immediate family member of the referring physician. The Final Rule defines "immediate family member" as husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; and spouse of grandparent or grandchild.

In-Office Ancillary Services Exception

The in-office ancillary services exception permits the physician owners of a medical group, and other members of the group, to refer patients to their own group for certain DHSs. It also permits physicians and medical groups to develop shared DHS facilities under certain circumstances.

The Final Rule expands the scope of DHSs protected by the in-office

ancillary services exception; provides a more flexible definition of a group practice which may qualify for the exception; relaxes the level of physician supervision required to meet the exception for certain DHSs; and allows certain independent contractor physicians to supervise DHSs. At the same time, the Final Rule narrows the ability of group practices to use "block lease" or other part-time arrangements to provide DHSs on a shared basis in a centralized building, such as an imaging facility, in which the groups do not routinely provide substantially the full-range of their non-DHS services. The Final Rule also raises some new issues that may require further clarification.

To qualify for the in-office ancillary services exception, the DHS must satisfy a number of conditions. First, the service must be one of the DHSs covered by the exception. Second, the service must be furnished by the referring physician or by a member of the referring physician's group practice (or by an individual supervised by such physicians or supervised by a "physician in the group"). If a group practice is involved, the group must meet the definition of a "group practice" under the Stark Law. Finally, the service must satisfy certain supervision, location and billing requirements. Each of these elements of the in-office ancillary services exception is discussed separately below.

DHSs Covered By the In-Office Ancillary Services Exception. The statutory in-office ancillary services exception protects referrals for any DHS, except (i) PEN and (ii) DME other than infusion pumps. The Final Rule expands DME covered by the in-office ancillary services exception beyond just crutches, as had been proposed under the proposed rule, to also include canes, walkers and folding manual wheelchairs. These DME items are protected if the following

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Before HCFA issued the Final Rule, many medical groups feared they would not meet the in-office ancillary services exception, primarily because they could not satisfy the “group practice” definition contained in the proposed regulations.

conditions are met: (i) the patient requires the item for ambulating or the patient requires the item to depart from the physician’s office; (ii) the item is furnished in the “same building” as part of the treatment for the specific condition for which the patient-physician encounter occurred; (iii) the item is furnished personally by the physician who ordered it, by another physician in the group practice or by an employee of the physician or group practice; (iv) the physician or group furnishing the item meets all DME supplier standards in 42 CFR §424.57(c); (v) the arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission; and (vi) all other requirements for the in-office ancillary services exception are satisfied.

In addition, under the Final Rule, physicians may dispense a blood glucose monitor (and one starter set of testing strips and lancets consisting of no more than 100 of each) under the in-office ancillary services exception, but only if the physician or group practice furnishes diabetes self-management training to patients for whom the blood glucose monitors are furnished. HCFA also clarifies that, in addition to these DME items, braces and collars (which are orthotics and not DME) are covered by the exception; that ambulatory infusion pumps, but not infusion pumps used to deliver PEN, are covered by the exception; and that splints are not considered DHSs and thus do not require an exception to be provided by a physician or group.

HCFA further clarifies that outpatient prescription drugs, chemotherapy drugs and allergen tests if administered in the physician’s office or if dispensed in the physician’s office and self-administered by the patient at home, are covered by the in-office ancillary services exception. HCFA has revised the definition of “furnished” in the physician’s office to

mean “furnished in the location where the service is actually performed upon a patient,” or “where an item is dispensed to a patient in a manner that is sufficient to meet Medicare billing and coverage rules.”

Furthermore, HCFA has withdrawn its proposal that physicians be prohibited from marking up any of these items when provided in-office to their patients.

Group Practice Definition. Before HCFA issued the Final Rule, many medical groups feared they would not meet the in-office ancillary services exception, primarily because they could not satisfy the “group practice” definition contained in the proposed regulations. The new “group practice” definition provides substantial relief. HCFA clarifies many aspects of the definition and revises it to better reflect how most modern medical groups are actually formed and operate.

The Final Rule defines a group practice as a physician practice that meets all of the following conditions: (i) it is a single legal entity; (ii) it has at least two physicians who are “members of the group”; (iii) each physician member of the group furnishes substantially the full range of “patient care services” that the physician routinely furnishes; (iv) at least 75 percent of the total patient care services of the group practice members are furnished through the group and billed under a billing number assigned to the group, and the amounts received are treated as receipts of the group; (v) members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice; (vi) the overhead expenses of, and income from, the practice are distributed according to methods determined before the receipt of payment for the services giving rise to the overhead expense or producing the

income; (vii) the group is a “unified business”; and (viii) no physician member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician (except under the special rule for productivity bonuses and profit shares, discussed below in the section entitled “Permissible Compensation Methodologies under the Final Rule”).

The following subsections discuss the required elements of a group practice.

Single Legal Entity. Under the Stark Law, a group practice must consist of two or more physicians practicing through a single legal entity. In the Final Rule, HCFA clarifies the single legal entity requirement and expands the types of entities that may qualify to include any organizational form recognized by the state in which the group practice establishes its legal status (including, but not limited to, a partnership, professional corporation, limited liability company, foundation, not-for-profit corporation, faculty practice plan or similar association). The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities or other persons or entities. The only exception to this rule is that the single legal entity may not be owned in whole or in part by a “medical practice that is an operating physician’s practice.” This is intended to prevent medical groups from banding together to form a joint practice primarily to share in-office referrals, although it is somewhat unclear exactly what constitutes “an operating physician’s practice.”

The single legal entity need not have any physician owners, but at least two physicians must be group members (*i.e.*, owners and/or physicians who provide services to patients as employees, *locum tenens* or on-call physicians of the group). Thus,

hospital owned or affiliated group practice entities can qualify as group practices as long as they include at least two practicing physicians. A hospital that directly employs physicians, however, cannot qualify as a group practice because the single legal entity must be formed primarily for the purpose of being a physician practice (and not for providing hospital services). Accordingly, a physician division of a hospital must be restructured as a wholly-owned subsidiary of the hospital to satisfy the single legal entity requirement in order for the physicians to qualify as a “group practice” that can take advantage of the in-office ancillary services exception.

A group practice may be owned by multiple entities (such as physicians, a hospital and/or others) as long as none of the owners is a separately operating physician practice. A group practice, however, cannot be comprised of separate group practices under common ownership or control through a hospital or practice management company. Thus, if a health system owns two separate group practice entities, to the extent they have a financial relationship with each other, cross referrals between the practices would not be protected by the in-office ancillary services exception (but may be protected by the indirect compensation exception). Referrals within either of the groups by members of the group would be protected. The single legal entity requirement is also not satisfied by other informal or loose confederations of physicians, a substantial purpose of which is to share profits from ancillary referrals.

The single legal entity that is a group practice may own a clinical laboratory or other legal entities (other than a separate operating physician’s practice) and still be considered a group practice. The single legal entity

requirement thus does not generally preclude the group practice from owning subsidiaries.

Member of the Group and the 75 Percent Tests. The “75 Percent Tests” (as defined below) are HCFA’s interpretation of the statutory requirements for a group practice that “substantially all” of the services of physician members must be provided through the group (the “Patient Care Services Test”), and physician “members of the group” practice must personally conduct at least 75 percent of the group practice’s patient encounters (the “Physician-Patient Encounters Test”) (the Patient Care Services Test and the Physician-Patient Encounters Test are referred to as the “75 Percent Tests”). Satisfaction of the 75 Percent Tests depends, in part, upon who qualifies as a “member of the group” and who qualifies as a “physician in the group.” (The definitions of “member of the group” and “physician in the group” also determine who is eligible to supervise in-office ancillary services and who is eligible to receive profit shares and productivity distributions from a group practice.)

Importantly, independent contractors and leased employees are not considered “members of the group” under the Final Rule. Their services are, therefore, not counted as group services for purposes of the 75 Percent Tests. Rather, “members of the group” are defined in the Final Rule only to include direct and indirect physician owners of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another wholly owned entity), a physician employee of the group practice (including a physician employed by an entity that has an equity interest in the group practice), on-call physicians and *locum tenens* physicians.

The elimination of independent contractors and leased employees (who typically provide more services outside the group than within it) from the definition of “members of the group” means that many more medical groups will be able to meet the Patient Care Services Test. The inclusion of on-call physicians and *locum tenens* physicians as members of the group should not lead to a different result with respect to this test, since it appears that only those patient care services they provide while substituting or covering for a member of the group are intended to count in determining compliance with the Patient Care Services Test. “Outside” services of *locum tenens* and on-call physicians thus do not reduce the group’s aggregate percentage of “inside” patient care services. Medical groups, however, may find it more difficult to satisfy the Physician-Patient Encounters Test because the encounters conducted by the group’s independent contractors and leased employees are not counted in the numerator as group encounters for purposes of the Physician-Patient Encounters Test.

Under the Final Rule, HCFA adopts the expanded definition of “patient care services” announced in the proposed regulations, which includes “tasks that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters; or generally benefit a particular practice.” Accordingly, patient care services now include consulting with other physicians, reviewing laboratory tests, training staff members, arranging for equipment and performing administrative and management tasks. Notably, teaching, administrative and research activities conducted by physicians outside of the group practice setting will not be counted against the group in determining compliance with the Patient Care Services Test.

The Unified Business Test has been modified in the Final Rule to expressly permit profit center accounting for medical groups on a site or specialty-specific basis.

In the Final Rule, HCFA adopts a more flexible approach to measuring patient care services compared to the proposed regulations. Under the proposed regulations, HCFA measured patient care services by the “total patient care time” each group member spent on such services. In the Final Rule, HCFA adopts the “actual time” measure, but only as a default standard. Alternatively, HCFA now permits group practices to adopt other measures (such as RVUs, patient encounters or revenues) provided such measures are reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable and documented. The data used to calculate compliance with the Patient Care Services Test must also be made available to HCFA upon request.

Special consideration was given to new group practices in reshaping the Patient Care Services Test. HCFA recognizes that physicians may transition into a new group over time, making it difficult for the new group, at the outset, to meet the Patient Care Services Test. For this reason, the Final Rule provides that during the start-up period for a new group, the group practice must make a reasonable, good faith effort to ensure that the practice complies with the Patient Care Services Test as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This start-up exception to the Patient Care Services Test does not apply when an existing group practice admits a new member or when an existing group practice reorganizes. Also, this special rule for new groups has not been extended to help groups meet the Physician-Patient Encounters Test.

Unified Business Test. The Unified Business Test has been modified in the Final Rule to expressly permit profit center accounting for medical groups on a site or specialty-specific basis.

This is a welcome change from the proposed regulations (in which the Unified Business Test first appeared), which would have required groups to adopt a “distribution system that is not based on each satellite office operating as if it were a separate enterprise.” In revising the Unified Business Test in the Final Rule, HCFA acknowledges that the prohibition on site specific accounting would have discouraged beneficial integration among medical groups and would have invalidated many *bona fide* group practice compensation arrangements.

Under the Final Rule, HCFA has crafted a more flexible Unified Business Test that better meets the goal of assuring that group practices are substantially integrated businesses, without overly micromanaging group structures, accounting or operations. To satisfy the new Unified Business Test, a group practice must have (i) centralized decision-making by a body representative of the group practice that maintains effective control over the group’s assets and liabilities; (ii) consolidated billing, accounting and financial reporting; and (iii) centralized utilization review. Most existing groups should be able to meet the first two requirements. However, the third element, centralized utilization review, may raise an issue for some groups, particularly if it is interpreted to mean that the group must conduct regular utilization review of its members, as opposed to merely having the authority to do so as necessary. This is an issue that may warrant further comment during the 90-day comment period on the Final Rule.

Methods of Distribution. Under the Stark Law, the overhead expenses of and income from the group practice must be distributed in accordance with methods “previously determined.” In the proposed regulations, HCFA interpreted this requirement to mean that the distribution method must be determined prior to incurrence of the invoice or costs. This proposal was criticized as overly restricting the group’s ability to adjust compensation periodically to reflect a physician’s contribution to the group or to pay discretionary bonuses. In the Final Rule, HCFA replaces the “prior to incurrence” rule with a “prior to receipt” rule—that is, methods of distribution of group practice revenue must be determined prior to receipt of payment for the services giving rise to the overhead expense or producing the income. HCFA also interprets this rule to permit groups to adjust their compensation methodologies prospectively (that is, with respect to payments not yet received) as often as they deem appropriate.

No Group Practice Attestation. In the Final Rule, HCFA eliminates the group practice attestation requirement contained in the proposed regulations that would have required physicians to certify, under penalties of perjury, that the group satisfies all of the definitional requirements to be a group practice.

Direct Supervision. To qualify for the in-office ancillary services exception, DHSs must be furnished personally by a referring physician or another physician member of the same group practice, or be furnished by individuals who are “directly supervised” by such physicians or “directly supervised” by a “physician in the group.” The purpose of the direct supervision requirement is to ensure that a nexus exists between the physicians in the group practice and the individual performing the ancillary services, in order to limit the in-office

ancillary services exception to services that are truly “ancillary” to the referring physician’s medical practice. Reversing its position from its proposed regulations, HCFA now permits in-office ancillary services to be supervised by independent contractors who qualify as “physicians in the group practice” (*i.e.*, physicians who provide services to the group’s patients in the group’s facilities, pursuant to a contractual arrangement with the group that satisfies the Medicare reassignment rules).

The direct supervision standard received the largest number of public comments of any of the proposed rules relating to the in-office ancillary services exception. This is because, in the proposed regulations, HCFA interpreted the direct supervision standard to require supervision by a physician who is physically present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed (although certain brief absences and lunch breaks were permitted). Commenters pointed out that the proposed requirement would mandate for certain DHSs a higher level of supervision than required by applicable Medicare coverage and payment rules (*e.g.*, plain films without contrast) and would result in wasteful and inefficient staffing practices. HCFA was persuaded by these comments to revise the direct supervision standard in the Final Rule.

Under the Final Rule, “directly supervised” is interpreted to mean that the supervision meets the level of supervision required under applicable Medicare and Medicaid coverage and payment rules for the specific services at issue. Applicable Medicare coverage policy defines three different levels of supervision (physical presence in room, physical presence in suite, and immediate availability that may be

Under the Final Rule, “directly supervised” is interpreted to mean that the supervision meets the level of supervision required under applicable Medicare and Medicaid coverage and payment rules for the specific services at issue.

off-site and by telephone) that are associated with particular procedures.

In addition, DHSs that are billed “incident to” physician services must meet the “incident to” supervision requirements, which requires physical presence in the office suite.

Location Requirement. The purpose of the location requirement is to ensure that services that qualify for the in-office ancillary services exception are part of the physician’s routine medical office practice and are not provided as part of a separate business enterprise. Under the Stark Law, covered services must be furnished in the same building in which the referring physician, or another physician who is a member of the same group practice, furnishes physician services unrelated to DHSs (the “same building” option).

Alternatively, with respect to a referring physician who is a member of a group practice, the covered services can be furnished in another building (the “centralized building”) used by the group practice for the provision of some or all of the group’s clinical laboratory services or for the centralized provision of the group’s DHSs (other than clinical lab services). The Final Rule broadens the same building option, which is available to both solo practitioners and group practices, but limits the centralized building option, which is available only to group practices.

Same Building. The “same building” rules provide the opportunity for physicians and medical groups in separate practices, under certain circumstances, to develop shared DHS facilities in the same building. It also applies to referring physicians in the same group who practice in the same building.

Stating that Congress did not intend the application of the in-office ancillary services exception to be dependent on the “nuances of architectural design,”

HCFA, in the Final Rule, modifies the definition of “same building” to mean a structure with, or combination of structures that share, a single street address assigned by the U.S. Postal Service. This definition reverses the position HCFA took in the proposed regulations that “same building” could not include multiple structures connected by tunnels or walkways. The same address approach, however, may produce anomalous results for physicians who practice in buildings on corner lots that have two mailing addresses and for physicians who practice in adjoining or nearby buildings with different addresses.

Moreover, under the Final Rule, “same building” does not include exterior spaces such as courtyards, lawns, driveways, parking lots or interior parking garages. Thus, the in-office ancillary services exception will not apply to referral services performed on mobile MRI or CT equipment, jointly owned by physicians practicing in the same building, if the vehicle housing the equipment is parked in the building’s parking lot. However, while “same building” does not include a mobile vehicle, van or trailer (although such vehicles may constitute a centralized building under the limited circumstances discussed below), the “same building” requirement otherwise does not preclude a group practice from moving equipment from office to office for the provision of DHSs within such offices, as long as the other “same building” requirements are met.

In addition to the same address requirement, the “same building” location test requires the following:

The “centralized building” option requires a group practice to operate a location where the group provides some or all of its clinical laboratory services or provides DHSs (other than clinical lab services) and an additional location where the group provides substantial physician services unrelated to DHSs.

- The referring physician (or another member of the same group practice) must furnish in the same building substantial physician services unrelated to the furnishing of federal or private pay DHSs. This is a significant change from the proposed regulations which did not specify any particular quantity of unrelated services to be furnished in the same building.
- The unrelated services furnished in the same building must represent substantially the full range of unrelated physician services that the physician routinely provides.
- The patient’s primary nexus with the referring physician (or his or her group practice) must be the receipt of physician services unrelated to the furnishing of DHSs.

These new standards raise factual questions that will leave uncertainty about the applicability of the in-office ancillary services exception in particular circumstances (*e.g.*, when a patient goes to an orthopedist for an x-ray, is the primary nexus a physician service (*i.e.*, diagnosis), or a DHS (*i.e.*, the x-ray?)).

As long as the foregoing “same building” requirements are met, a “same building” can include a SNF, a patient’s home or other nontraditional office setting. HCFA has also fashioned a special rule for home care physicians about which it has solicited further comments. Under the special rule, home care physicians satisfy the “same building” test if the physician’s principal medical practice consists of treating patients in their private homes (which do not include nursing, long term care or other facilities), and the physician or an accompanying staff member provides a DHS in the private home contemporaneously with a

physician service (provided by the referring physician) that is not a DHS.

Centralized Building. The “centralized building” option requires a group practice to operate a location where the group provides some or all of its clinical laboratory services or provides DHSs (other than clinical lab services) and an additional location where the group provides substantial physician services unrelated to DHSs. The Final Rule defines “centralized building” to mean all or part of a building (including a mobile vehicle, van or trailer) that is owned or leased on a full-time basis (*i.e.*, 24-hours per day, seven days per week, for at least six months) by a group practice and that is used exclusively by the group practice.

The exclusivity requirement precludes use of a centralized building for shared facilities. The Final Rule, therefore, prohibits group practices from “block leasing” or otherwise sharing time on MRI or CT equipment at a jointly owned imaging center (that does not meet the “same building” definition). Part-time centralized DHS arrangements are precluded. However, since a centralized building can include a van, a single group practice that exclusively leases mobile MRI, CT or other equipment may circulate the equipment among its own group practice locations. Thus, a group practice may have more than one centralized location for the provision of DHSs.

Billing Requirement. Under the Stark Law, to qualify for the in-office ancillary services exception, the DHS must be billed under one of the following three arrangements: (i) by the physician performing or supervising the service; (ii) by the group practice of which such physician is a member, under that group practice’s billing number; or (iii) by an entity wholly owned by the referring or supervising physician or

the referring or supervising physician's group practice. The Final Rule confirms that a group may bill under multiple provider numbers.

Under the Final Rule, HCFA creates a fourth permissible billing arrangement. DHSs that are performed by an independent contractor physician may be billed by a group (and qualify for the exception) if the independent contractor physician is a "physician in the group." To be a physician in the group, the independent contractor must reassign his or her Medicare receipts to the group under the health care delivery services exception to the general reassignment prohibition.

Referring physicians and their group practices may also bill under the in-office ancillary services exception for services provided by an entity that is "wholly owned" by the referring or supervising physicians or their group practice. Alternatively, if the wholly owned entity qualifies to bill under its own provider number, it need not use a number assigned to the physician or group practice that owns it. Note that the "wholly owned" requirement precludes billings by joint venture entities from qualifying for protection under the in-office ancillary services exception.

Billing for the physician or group may be performed by a billing agent that bills for services under the provider's billing number(s) (*i.e.*, as agent) and not under the billing company's own billing numbers (*i.e.*, not as principal). Any billing agent arrangement must also comply with applicable reassignment rule requirements. Failure to comply with such reassignment rules would disqualify the physician or group from relying on the in-office ancillary services exception.

Physician Services Exception

The Final Rule provides that compensation is set in advance if either the

The physician services exception overlaps somewhat with the in-office ancillary services exception, but it applies only to the professional component of DHSs. In particular, the physician services exception exempts from the general self-referral prohibition certain physician services furnished personally by another physician in the same group practice as the referring physician or furnished under the personal supervision of another physician in the same group practice as the referring physician. Protected "physician services" include professional services performed by physicians (*i.e.*, surgery, consultation, diagnosis, therapy services and home, office and institutional calls) but not services performed by non-physicians or "incident to" services.

In the Final Rule, HCFA makes two modifications to the physician services exception that mirror changes made to the ancillary services exception. First, an independent contractor who qualifies as a "physician in the group" may make or receive referrals and supervise services within a group under the protection of the physician services exception. Second, HCFA is interpreting the "personal supervision" requirement to mean the level of supervision required under the Medicare payment and coverage rules applicable to the particular physician service at issue. These provisions slightly expand the reach of the physician services exception, which is generally regarded as being of limited use.

Permissible Compensation Methodologies Under the Final Rule

As noted above in connection with the in-office ancillary services exception, the Final Rule includes special rules relating to bonus or profit distributions to physicians in a group. These rules in turn affect the group's eligibility to

be treated as a “group practice” that can take advantage of the in-office ancillary services exception. The Final Rule also includes other provisions that affect physician compensation under the exceptions included in the Final Rule, as well as the exceptions that will be included in the Phase II rule.

“Set in Advance” and “Volume or Value” Definitions. The Final Rule seeks to simplify the analysis of compensation arrangements under Stark by applying uniform definitions to two crucial concepts that appear in most of the compensation exceptions: the requirement that compensation be “set in advance” and the “volume or value” standard.

“Set in Advance” Standard. The requirement that aggregate compensation be “set in advance” appears in the lease, personal services and new fair market value and academic medical center exceptions. The Final Rule provides that compensation is set in advance if either the aggregate amount over the term of the agreement is fixed or if payment is calculated based on a fixed time-based or per unit of service-based amount. Payment to a physician for services on an hourly basis or a fixed fee schedule would satisfy this requirement, as would payment to a physician lessor on a per use or “per click” basis, so long as the rate does not vary during the term of the agreement.

Percentage compensation - whether of revenue, income or expenses - is not considered “set in advance” under the Final Rule. A percentage of a fixed fee schedule is acceptable (e.g., 60% of a fixed chargemaster). However, a

*A physician in a group practice
may be paid a share of the overall
profits of the group derived from
DHSs or a productivity bonus
based on services personally
performed by that physician
or “incident to” such services,
provided the share or bonus*

include a requirement that the compensation not take into account “the volume or value of referrals” of DHS. Most (with the notable exception of the statutory employment exception) also require that the compensation not take into account “other business generated between the parties.” Under the Final Rule, compensation will not be deemed to take into account “the volume or value of referrals” if it is fair market value and does not vary during the course of the arrangement in any manner that takes into account referrals of DHS. Additionally, compensation based on a “per use,” “per service” or “per time period” basis will not be deemed to violate the “volume or value” standard even if the calculation includes services based on the physician’s own DHS referrals, provided the unit rate is fair market value and does not vary over the term of the agreement. For example, if a physician leases a CT machine to a hospital on a “per click” basis, compensation to the physician could include the “clicks” generated by the physician’s own referrals of CT to the hospital without running afoul of the “volume or value” standard (again, provided the click rate is fair market value and does not vary over the term of the agreement). Similarly, compensation will not be deemed to take into account “other business generated between the parties” if it is fair market value and does not vary during the course of the arrangement in any manner that takes into account non-DHS referrals or other business (including commercial and private pay business) generated by the referring physician. Put another way, payments to physicians cannot include any additional amount attributable to the non-DHS business they generate for the entity.

Paying Physicians to Practice. Most physicians practice medicine as part of a larger entity that also furnishes DHS, whether a small group, large multispecialty practice or integrated

delivery system. In order for the physician to refer DHS to the entity, either the compensation the physician receives from that entity must meet an exception (*e.g.*, the employment, personal services arrangement or fair market value compensation exception) or the referral for DHS must itself meet an exception (typically the in-office ancillary services exception). The Final Rule clearly establishes a hierarchy of three categories of practicing physician for purposes of compensation. First, physicians in a group practice (group practice owners, employees and non-owner independent contractors who are billed by the group under a valid reassignment) may receive compensation under the most liberal rules. Next, employed physicians who do not qualify as physicians in a group practice are subject to stricter compensation rules. Finally, independent contractors who do not qualify as physicians in a group practice are subject to the most limiting compensation rules.

Physician in a Group Practice.

Under the Final Rule, overall profits of a group practice not derived from DHS can be segregated and distributed to the physicians in the group practice essentially without limitation. A physician in a group practice may be paid a share of the overall profits of the group derived from DHSs or a productivity bonus based on services personally performed by that physician or “incident to” such services, provided the share or bonus calculation is not directly related to the volume or value of the physician referrals for DHSs.

The Final Rule defines “overall profits” as either all of the group’s profits from Medicare- and Medicaid-covered DHSs or the profits of any component of the group consisting of at least five physicians. This will permit segregation and division of DHS profits in a large group either by

geographic location or by specialty, so long as each component consists of at least five physicians. The Final Rule explicitly approves DHS profit distributions on a per capita basis and distributions on the basis of the group’s allocation of revenues for services unrelated to DHSs (whether paid by Federal or private payors). Distributions in either of these ways are deemed not to be directly related to a physician’s DHS referrals and are, therefore, permissible.

A profit share may be divided in any other reasonable and verifiable manner that is not directly related to the volume or value of any physician’s referral for DHSs. As HCFA notes, however, in such cases the group “essentially bears the risk of noncompliance.” Finally, the group may allocate DHS profits in any fashion so long as the group’s revenues from DHSs constitute less than 5 percent of the group’s total revenues, and the allocated portion of the DHS profits to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

The Final Rule similarly provides express approval for productivity bonuses calculated based on the physician’s total patient encounters or work RVUs. Productivity bonuses may also be calculated in any reasonable and verifiable manner that is not directly related to the volume or value of the physician’s referrals for DHSs. Finally, a productivity bonus can include DHS revenues allocated in any matter if the group’s revenues from DHSs constitute less than 5 percent of the group’s total revenues, and the allocated portion of those revenues to any physician constitutes 5 percent or less of his or her total compensation from the group.

Under the Final Rule, it appears that productivity bonuses may take into account both DHSs personally

performed or provided by the referring physician and DHSs “incident to” the referring physician’s services. For example, while under the Final Rule, an echocardiography interpretation is a DHS, a cardiologist who refers the patient for the echo and personally performs the read can receive a productivity bonus that takes into account those reads (for example, on the basis of RVUs). Similarly, an injection billed as “incident to” the referring physician’s service can be credited to that physician for purposes of a productivity bonus. For large groups, however, it may be a challenge for information systems to segregate personally-furnished DHS from other DHS; the segregation could not be done simply on the basis of CPT/HCPCS codes. If a group desires to utilize both overall profits and productivity bonuses, the calculation becomes complex. “Overall profits” is defined in such a way that profits from DHS personally performed or provided by the referring physician (as well as DHS “incident to” the referring physician’s service) would need to be included in the overall profits pool, even if a physician has received credit for that same DHS in connection with a productivity bonus.

The question of whether that cardiologist could receive credit for the technical component of the echocardiography service is less clear. On one hand, the commentary on “incident to” services strongly suggests that DHSs that are “incident to” a physician’s personal service can be included in a productivity bonus. The technical component of echocardiography could arguably satisfy all the requirements for “incident to” coverage (which include direct supervision by a physician in the group). In other places in the commentary, however, HCFA suggests that generally there should be no direct correlation between compensation and the volume or value

of the physician’s DHS referrals “regardless of whether the services are personally performed.” This statement is especially confusing in that HCFA has defined a personally-furnished DHS as not constituting a “referral” and is difficult to reconcile with HCFA’s express approval of productivity bonuses based on “incident to” services. Finally, it is not clear how a productivity bonus based on “incident to” DHS referred by the physician does not vary directly with such DHS referrals.

It is clear that productivity bonuses could not include DHS that were not directly supervised by a physician in the group practice. While some services (*e.g.*, plain films without contrast) could qualify as in-office ancillary services under the Final Rule with only general supervision, a service rendered with only general supervision would not be “incident to” the physician’s service and, therefore, would need to be distributed, if at all, on some other permitted basis, *e.g.* as a share of overall DHS profits.

Employed Physicians Outside a Group Practice. For employed physicians outside a group practice (for example, an employee of a clinic that furnishes DHS but does not qualify as a “group practice”), compensation will need to satisfy the employee exception. (There is a statutory employment exception in the Stark Law itself; the corresponding regulatory exception will be in Phase II of the Stark Law rule.) The preamble to the Final Rule makes clear that such employed physicians could receive a productivity bonus based on DHSs personally performed or provided by the physician but could not receive a productivity bonus based on DHSs furnished “incident to” the physician’s service. While not entirely clear, the

preamble also suggests the employed physician might even be precluded from receiving a productivity bonus for *non-DHS* “incident to” services. HCFA states in its commentary that for employed physicians, “the amount of compensation for personal productivity is limited to fair market value for the services they personally perform” excluding “incident to” services. It would appear from the statute that employed physicians could be paid on a percentage basis that excludes DHS (for example, a percentage of collections from services personally furnished) since the statutory exception does not include a requirement that compensation be “set in advance.”

Independent Contractor Physicians Outside a Group Practice.

Compensation of an independent contractor physician outside a group practice would need to satisfy the personal services exception (a statutory exception that will be addressed by regulation in Phase II) or the new fair market value arrangement exception (discussed below). These exceptions require that compensation be set in advance, and percentage arrangements would, therefore, be impermissible (even if Medicare and Medicaid were carved out). Payment on an hourly or per service basis (*e.g.*, a fixed fee schedule or fixed amount per RVU or patient encounter) would be permissible, excluding services “incident to” the physician’s services.

Special Rule Regarding Contractual Requirement to Refer. If the physician’s compensation arrangement includes a condition that the physician make referrals to a particular provider, practitioner or supplier, the Final Rule indicates that compensation must be fixed in advance for the term of the agreement. Additionally, the arrangement must not violate the anti-kickback statute, and the referral requirement must include exceptions where the patient expresses a contrary

preference, where the patient’s insurer directs the referral to a particular provider, practitioner or supplier, or where the referral is not in the patient’s best medical interests in the physician’s judgment.

Services Furnished Under Arrangements. Under the Final Rule, hospital services furnished “under arrangements” with an outside vendor are considered to be furnished by the hospital, not the vendor. Thus, for the purposes of the Stark Law, a physician’s ownership interest in the vendor is not an ownership interest in an entity furnishing hospital services. Nevertheless, the hospital’s compensation to the vendor will create a financial relationship that will require an exception if the vendor is physician-owned.

For example, if a group of urologists form an LLC to furnish lithotripsy services “under arrangements” to a hospital, each urologist will have an indirect compensation arrangement with the hospital that will need to meet the indirect compensation exception. This exception requires that compensation not take into account the value or volume of referrals or other business generated. Payment on a fair market value per-service basis would be permissible, even if the payments included services referred by the urologist. HCFA cautions, however, that fair market value for these purposes cannot be set by the price other entities with referring urologists are charging. Instead, it must be based on the price set by non-referring entities or, if none are available, based on a reasonable alternative measure such as return on investment. HCFA specifically condemns an arrangement where a physician-owned entity rents a lithotripter on a per-use basis from a third party and re-sells it to the hospital at a higher rate.

While HCFA states in the Final Rule that “under arrangements” transactions can generally be structured to satisfy the lease, personal services arrangement or fair market value exception, unless the arrangement is between a hospital and an individual physician, only the indirect compensation exception would appear to be available. Unlike the lease and personal services exception, the indirect compensation exception requires that the arrangement not violate the anti-kickback statute. HCFA repeatedly cautions in the Final Rule that per click arrangements may violate the anti-kickback statute. (“Despite the obvious potential for abuse...we are permitting ‘per use’ payments even when the physician is generating the referrals. We wish to make clear that these arrangements may violate the anti-kickback statute.” 66 Fed. Reg. 878.) Additionally, the Final Rule highlights arrangements in which hospital space is leased to physician groups who use the space to provide services to the hospital “under arrangements” that were formerly furnished directly by the hospital, noting that these raise “significant issues” under the anti-kickback statute. “Under arrangements” relationships will, therefore, require careful structuring both under the anti-kickback statute and the Final Rule.

because it fills certain gaps among the various statutory exceptions for employment, personal services and lease arrangements. The exception protects compensation arrangements between an entity and a physician (or immediate family member) or group of physicians (even if the group does not meet the definition of “group practice”) for the provision of items or services by the physician or group if the arrangement meets the following six conditions: (i) the arrangement is in writing, signed by the parties, and covers identifiable items and services; (ii) the time frame for the arrangement is specified and may be for less than one year provided the parties enter into only one arrangement for the same items or services during the course of a year; (iii) the compensation is “set in advance” (according to the definition described above), is consistent with fair market value and is not determined in a manner that takes into account “the volume or value of referrals” or any “other business generated between the parties” (according to the definitions described above); (iv) the transaction is commercially reasonable and furthers the legitimate business purposes of the parties; (v) the arrangement either meets an anti-kickback statute safe harbor, has been approved by the OIG in an advisory opinion or does not violate the anti-kickback statute; and (vi) the services to be performed do not involve the counseling or promotion of a business arrangement that violates state or federal law.

The Final Rule no longer includes the burdensome requirement that the agreement either must include or cross-reference all arrangements between the parties.

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compensation exception was included in the proposed rule, and the ultimate form of this exception was a much anticipated provision of the Final Rule

There are several important differences between the proposed rule and the Final Rule. The Final Rule no longer includes the burdensome requirement that the agreement either must include or cross-reference all arrangements between the parties. The proposed requirement that the arrangement must be in compliance with the anti-kickback statute has been replaced with a requirement that the arrangement not violate the anti-

kickback statute, which is a more appropriate standard with respect to a criminal statute that describes prohibited conduct. Nevertheless, it will still be difficult to determine with any level of certainty whether this requirement is met, given that the anti-kickback statute is a criminal statute where violation depends on intent. The inclusion of this requirement here and in other compensation exceptions introduces a subjective element into what is intended to be a “bright line” test. HCFA makes matters worse by stating in the preamble to the Final Rule that if one of the parties to an arrangement intends to induce referrals but the other party does not, the exception does not apply.

The requirement that compensation be “set in advance” somewhat limits the scope of the exception, since it precludes percentage and other formula-based arrangements that are not within the scope of the Final Rule’s definition of “set in advance.” However, the Final Rule’s “volume or value of referrals” standard broadens

Critics of the proposed rule convinced HCFA that academic medical centers raise questions under the Stark Law that are not adequately addressed by existing exceptions, and HCFA was also persuaded that there was sufficient evidence of congressional intent to address the special circumstances of physicians practicing in academic medical settings.

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fair market value exception, the arrangement may give rise to an indirect compensation arrangement between the entity providing DHSs and individual physicians in the group. Those indirect compensation arrangements would have to meet the exception for indirect compensation arrangements, described above, in order for the individual physicians in the group to refer to the entity.

Academic Medical Center

Exception. Faculty practice plans typically are involved in complex compensation arrangements, including compensation not only from the faculty practice plan itself to physicians, but also compensation from a hospital or other health care facility to the faculty practice plan or physicians and *vice versa*. Many elements of these arrangements may meet the same exceptions available to other physician groups (*e.g.*, the in-office ancillary services exception may cover referrals for DHSs within a faculty practice plan or component that qualifies as a “group practice”). However, certain arrangements that might be problematic in a private practice setting and, therefore, are not eligible for an existing exception are common in the context of an academic medical center and may be viewed as furthering the teaching, research and community service mission of the organization (*e.g.*, a hospital’s provision of office space to the faculty practice plan). Critics of the proposed rule convinced HCFA that academic medical centers raise questions under the Stark Law that are not adequately addressed by existing exceptions, and HCFA was also persuaded that there was sufficient evidence of congressional intent to address the special circumstances of physicians practicing in academic medical settings.

The new academic medical center exception applies to both ownership

and compensation relationships and includes numerous requirements intended to ensure that only physicians that are truly engaged in academic medical practice, and entities that are truly engaged in teaching, research and community service, are protected. An “academic medical center” consists of an accredited medical school, an affiliated tax-exempt faculty practice plan and one or more affiliated hospitals in which a majority of the medical staff consists of physicians who are faculty members, and the majority of all hospital admissions are made by physicians who are faculty members. (The Final Rule is unclear as to whether an academic medical center must have all of these entities to qualify for the exception or whether an academic medical center that consisted of only a medical school and a hospital, but no separate faculty practice plan, could also qualify.) These entities, plus any teaching facility, institution of higher education or departmental professional corporation are referred to as “components” of the academic medical center.

The exception covers services provided by an academic medical center if all of the following conditions are met: (i) the referring physician: is a *bona fide* employee of a component of the academic medical center, is licensed to practice medicine in the state, has a *bona fide* faculty appointment at the affiliated medical school, and provides and is compensated for substantial academic or clinical teaching services in connection with his or her employment by the academic medical center; (ii) the total compensation paid for the previous 12-month period (or

The Final Rule provides additional flexibility by eliminating the \$50 per gift limit so, for example, an entity could give a physician one gift per year valued at up to \$300 or two or more

referrals or other business generated by the referring physician; (iii) all transfers of money among the components of the academic medical center directly or indirectly support teaching, indigent care, research or community service activities (including patient care), the relationship of the components of the academic medical center is set out in a written agreement adopted by the governing body of each component, and money paid to a referring physician for research must be used solely to support bona fide research; and (iv) the referring physician’s compensation arrangement does not violate the anti-kickback statute.

Although the academic medical center exception apparently is intended to recognize that the financial relationships among components of a *bona fide* academic medical center do not raise the concerns underlying the Stark Law, and while most academic medical centers will be able to comply in most respects with the exception, it may be difficult to ensure that every element of the exception is met. For example, academic medical centers typically have complex compensation formulas that may not meet the rather narrow “set in advance” standard of the Final Rule, which does not permit percentage arrangements.

Therefore, as a practical matter, academic medical centers may find it easier to rely on other exceptions (*e.g.*, the in-office ancillary services exception, employment exception and indirect compensation exception) to cover the various relationships among components of the academic medical center. The new definition of and exception for indirect compensation arrangements should be particularly useful to academic medical centers, since many financial arrangements involving components of the academic medical center either (i) will not meet the definition of an indirect compensation arrangement, so there

would be no need to meet an exception or (ii) will be indirect compensation arrangements for individual referring physicians, and the indirect compensation exception is more flexible than the academic medical center exception.

Non-Monetary Compensation Up to \$300. The proposed rule included an exception for *de minimis* compensation not to exceed \$50 per gift and an aggregate of \$300 per year, so low value, non-cash gifts to physicians (*e.g.*, holiday gifts) would not trigger the Stark Law referral prohibition. The Final Rule provides additional flexibility by eliminating the \$50 per gift limit so, for example, an entity could give a physician one gift per year valued at up to \$300 or two or more gifts so long as the total does not exceed \$300. The compensation/gift may take the form of items or services but not cash or cash equivalents.

The proposed rule's requirement that all "similarly situated" physicians be offered the gift has been eliminated. Instead, the Final Rule provides that the compensation may not be determined in a manner that takes into account the volume or value of referrals. Also, the compensation may not be solicited by the physician or the physician's practice. Therefore, a physician cannot demand free items in exchange for doing business with the entity or availability to listen to a sales pitch from an entity that provides DHSs. The exception also requires that the compensation arrangement not violate the anti-kickback statute. Of course, this creates somewhat of a dilemma since the OIG has explicitly declined to adopt an anti-kickback statute safe harbor for *de minimis* compensation. Nevertheless, given the intent-based nature of the anti-kickback statute, it is unlikely that gifts that meet the monetary and other standards of the exception would

trigger the criminal penalties of the anti-kickback statute.

Note that the exception protects gifts to physicians, but gifts to a group practice as a whole would not meet the exception. Therefore, the exception would not cover a single gift or multiple gifts over the course of a year from an entity to a large group practice valued in the aggregate at \$300 times the number of physicians in a group.

Medical Staff Incidental Benefits. Comments to the proposed rule had pointed out that, even with the *de minimis* exception for gifts up to \$300 per year, certain common non-abusive medical staff benefits such as free parking and free meals for physicians while they are at the hospital treating patients or performing other hospital-related duties could easily add up to more than \$300 per year. Therefore, the Final Rule includes an additional new exception for medical staff incidental benefits. This exception applies only to benefits provided by a hospital, while the non-monetary compensation exception applies to compensation from any entity. As in the case of the non-monetary compensation exception, benefits may not take the form of cash or cash equivalents, may not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties and must not violate the anti-kickback statute. The medical staff benefit must be offered to all members of the medical staff, regardless of referral volume or other business generated between the parties. The benefit may be offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients and may be provided and used only on the hospital's campus. Compensation must be reasonably related to the provision of, or designed to facilitate, the delivery of medical services, and

prepaid health plans or their directly or indirectly contracted providers and suppliers.

must be consistent with the types of benefits offered to medical staff members at other similarly situated hospitals. Finally, the compensation must be of low value (less than \$25) with respect to each occurrence (e.g., each meal).

Compliance Training. The new compliance training exception explicitly acknowledges that, while compliance training provided by a hospital to physicians in the community may arguably constitute remuneration to the physicians, this type of activity does not raise concerns under the Stark Law and indeed was explicitly approved in the OIG’s Compliance Program Guidance for Individual and Small Group Physician Practices issued in September 2000. The compliance training must take place in the local community or service area (i.e., cannot be used as a subterfuge for free trips) and may include training

The Final Rule includes a new exception that protects referrals of Medicare beneficiaries who are enrolled in employer group health and commercial managed care plans that place physicians at financial risk.

Prepaid Health Plan Exception. The Stark Law’s self-referrals exception does not apply to services furnished by Medicare prepaid health plans or their directly or indirectly contracted providers and suppliers (the “Prepaid Health Plan Exception”). This exception protects only those referrals of, and services provided to, persons

enrolled in one of the following prepaid health plans:

- coordinated care plans offered by Medicare+Choice organizations;
- health maintenance organizations and competitive medical plans under Section 1876 of the Social Security Act;
- health care prepayment plans described in section 1833(a)(1)(A) of the Social Security Act;
- a qualified health maintenance organization under section 1310(d) of the Public Health Service Act; and
- certain prepaid Medicare managed care demonstration projects.

The Final Rule addresses only Medicare prepaid health plans. Phase II will address Medicaid prepaid health plans.

The Prepaid Health Plan Exception permits a physician to refer enrollees of Medicare prepaid health plans directly to the health plan or to any provider or supplier of DHS that contracts directly (“first tier contractor”) or indirectly (“downstream contractor”) with the health plan, even though the physician has an ownership or compensation relationship with the health plan that does not meet another exception to the Stark Law.

The Prepaid Health Plan Exception only protects referrals of patients enrolled in Medicare prepaid health plans, and it does not protect referrals of patients enrolled in any other product offered or administered by the organization (e.g., a Medicare beneficiary who is enrolled, by virtue of current employment or retiree status, in a health plan that is either

primary or secondary to traditional Medicare fee-for-service coverage). Compensation paid to a physician for services furnished to enrollees of other products offered or administered by the organization would need to meet another exception to the Stark Law, such as the risk sharing arrangements exception discussed below or the personal services exception, in order to protect DHS referrals of Medicare enrollees.

The exception does not protect referrals of Medicare patients who are not enrolled in any product offered or administered by the organization, when those patients are referred directly to the organization or an entity owned by the organization for the provision of DHS. For example, the exception would not protect referrals of such patients to a clinical laboratory owned or operated by the organization where the referring physician has a protected compensation arrangement with the organization's Medicare prepaid health plan. Although protection would not be available under the Prepaid Health Plan Exception, it might be available under another exception to the Stark Law, such as the indirect compensation exception.

Risk Sharing Arrangements. The Final Rule includes a new exception that protects referrals of Medicare beneficiaries who are enrolled in employer group health and commercial managed care plans that place physicians at financial risk (the "Risk Sharing Arrangements Exception"). This exception, unlike the Prepaid Health Plan Exception, can protect DHS provided to Medicare beneficiaries who are enrolled in traditional Medicare fee-for-service and also have primary or secondary group health coverage through their current or former employer.

Under the Risk Sharing Arrangements Exception, payments to a physician by a managed care organization or

independent physicians association, either directly or indirectly through the physician's subcontracting arrangement with a first tier contractor, do not implicate the Stark Law so long as (i) the compensation is paid pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses and risk pools); (ii) the compensation is for services provided to "enrollees" of a "health plan"; and (iii) the arrangement does not violate either the anti-kickback statute or any law or regulation governing billing or claims submission.

HCFA borrowed the definitions of "enrollee" and "health plan" from the anti-kickback statute safe harbor regulations. See 42 CFR § 1001.952(l). Generally speaking, health plans include (i) HMOs and PPOs that charge a premium regulated by a state insurance or enabling statute; (ii) self-funded employer plans; (iii) union welfare funds; and (iv) plans operated in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a state health care program.

Physicians do not have financial relationships with other network providers and suppliers solely on the basis of their parallel compensation relationships with the health plan. However, the Risk Sharing Arrangements Exception does not protect independent financial relationships among network providers and suppliers (*e.g.*, a physician's ownership interest in an imaging facility or compensation relationship with a clinical lab for serving as medical director). Such independent financial relationships must themselves meet an exception to the Stark Law or DHS referrals among the parties to those arrangements would be prohibited. Like the Prepaid Health Plan Exception, the Risk Sharing Arrangements Exception does not protect referrals of Medicare patients who are not enrolled in a health plan

when those patients are referred for DHS directly to the organization offering or administering the health plan, or an entity owned by the organization. Although protection would not be available under the Risk Sharing Arrangements Exception, it might be available under another exception to the Stark Law, such as the personal services exception or the indirect compensation exception.

Ownership Interests in Managed Care Organizations. The Final Rule includes a revised definition of “entity” that permits physicians to refer Medicare patients to health plans and managed care organizations (MCOs) in which they have an ownership interest, including health maintenance organizations, provider-sponsored organizations and independent practice associations. However, this protection does not extend to referrals of Medicare patients to a health plan (as defined in the Risk Sharing Arrangements Exception) or MCO that furnishes DHS directly (*e.g.*, through an employee) or that operates a facility (as defined in the Medicare reassignment rules at 42 CFR § 424.80(b)(2)) that could accept reassignment from an employee or non-employed third party that furnishes the DHS on behalf of the facility.

Under this revised definition, an entity is considered to be furnishing DHS if the entity receives payment from Medicare for the DHS either directly, upon assignment from the patient or upon reassignment by another provider or supplier. However, a health plan or an MCO that accepts reassignment from another provider or supplier, is not an entity furnishing DHS for purposes of the Stark Law, except in the limited circumstances explained above. Accordingly, a physician with an ownership interest in a health plan or MCO that receives Medicare

payment for DHS solely on the basis of a reassignment does not have a financial relationship with an entity furnishing DHS when the physician refers Medicare patients to the health plan or MCO or their respective network providers.

Physicians having a permissible ownership interest in a health plan or MCO should be alert to indirect financial relationships created by the ownership interest and to other direct and indirect financial relationships the physician may have with the health plan, the MCO or other providers and suppliers in the health plan’s or MCO’s provider network. Those relationships may need to meet another exception to the Stark Law, such as the Risk Sharing Arrangements Exception, the indirect compensation exception or the personal services exception.

If you have any questions or concerns regarding the impact of the Final Rule on your organization's financial arrangements with referring physicians, please contact your regular MW&E lawyers or one of the following lawyers:

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