I. Introduction

The Health Care Financing Administration (“HCFA”) of the U.S. Department of Health and Human Services recently issued Phase I of its long-overdue final rules on the Stark II physician self-referral law. 66 Fed. Reg. 856 (Jan. 4, 2001) (“the final rules” or “Phase I”). The rules, which can be accessed on the Federal Register web site at www.access.gpo.gov/su_docs/aces/fr-cont.html, contain many significant changes from the proposed rules issued on January 9, 1998. The effective date of the pertinent provisions of the Phase I rules is January 4, 2002. The final rules were issued with a 90-day comment period, which has since been extended another 60 days until June 4, 2001. Comments submitted during this period will be considered by HCFA when it issues Phase II of the rules sometime in the not-so-near future. The agency also issued an interim final rule with a comment period setting forth the process for private parties to obtain advisory opinions on arrangements subject to Stark II.

Phase I covers the following provisions of the Stark statute:

- the prohibition on physician self-referrals;
- the definitions of key terms, including the definition of “group practice” and “designated health services;”
- the general exceptions that apply to both ownership and compensation relationships, including the in-office ancillary services exception.

In addition to addressing comments on Phase I, Phase II will cover other exceptions not dealt with in Phase I, including exceptions for specific compensation arrangements, as well as reporting requirements and sanctions. A question and answer document on the rule can be found on HCFA’s web site at www.hcfa.gov/medlearn/faqphys.htm.

II. Background on Stark II

Stark II is the federal statute (42 U.S.C. § 1395nn) that prohibits a physician from making a referral to an entity for the furnishing of “designated health services” (“DHS”) covered by Medicare if the physician (or an immediate family member of the physician) has a financial relationship with that entity, unless a statutory exception exists. The statute also prohibits an entity from submitting a claim to Medicare, or to any other person or entity, for DHS provided pursuant to a prohibited referral. Other sections of the Social Security Act apply the self-referral ban to Medicaid services. DHS include the following categories of services:

- clinical laboratory services;
- physical therapy services;
- occupational therapy services;
- radiology services (including X-rays, ultrasound or other imaging services, computerized axial tomography, MRI, radiation or nuclear medicine and diagnostic mammography services, including the professional component of these services);
- radiation therapy services;
- durable medical equipment (“DME”) and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

A financial relationship is defined to be either an ownership interest or a compensation arrangement. Violations of Stark II carry severe monetary penalties and in some cases exclusion from Medicare. The statute contains numerous exceptions that apply to both ownership and compensation arrangements, and those that apply just to one or the other.

It is important to note that Stark II must be analyzed separately from the Medicare-Medicaid anti-kickback law, which broadly precludes payments in exchange for referrals of program-related items or services. Compliance with Stark II does not necessarily ensure compliance with the anti-kickback statute and vice versa. For instance, Stark II generally does not apply to referrals involving the furnishing of physician services; the anti-kickback law does. Unfortunately, the final rules do little to clarify how the agency will treat arrangements that comply with a Stark II exception, but do not fall within one of the several established safe harbors for the federal antikickback statute or vice versa.

### III. Key Changes in Final Rules

The final rules contain several substantial revisions to the proposed rules, including, but not limited to, the following:

- Clarification of the definitions of DHS and generally linking DHS to CPT and the HCFA Common Procedure Coding System (“HCPCS”) codes.

- Creation of an exception for entities receiving prohibited DHS referrals that did not know or have reason to know the identity of the referring physician. The “did not know or have reason to know” standard includes an implied duty of reasonable inquiry, but does not create a requirement that each referral be examined to determine whether a financial relationship exists. The rule also excludes implants used in ambulatory surgical centers (“ASCs”), preventive screenings, and immunizations. DHS that are included in composite payment rates to ASCs are also excluded.

- Clarification of the concept of “indirect financial relationship” and creation of a new exception for indirect compensation relationships.

- Substantial broadening of the in-office ancillary services exception by easing the criteria for qualifying as a group practice, allowing sharing of DHS facilities with other groups, conforming the direct supervision requirements to HCFA coverage and payment policies for the specific services, expanding the definition of supervising physician to include independent contractors, and clarifying that groups with only one owner can qualify as a group practice if the practice employs at least one other non-owner physician.

- Exclusion of DHS personally performed by the referring physician from the definition of “referral.”

- Creation of new exceptions for risk sharing arrangements between physicians and commercial and employer-sponsored managed care plans; compensation of faculty in academic medical centers; nonmonetary compensation arrangements up to $300 per year; hospital medical staff incidental benefits; fair market value compensation arrangements; and post-cataract eyeglasses and contact lenses.

- Interpretation of the “volume or value” standard used in many of the law’s compensation exceptions as permitting unit of service or unit of time-based payments (for example, “per-click” arrangements), as long as those measures are set at fair market value and do not vary over time. However, the rule confirms that percentage-based compensation arrangements are generally not permitted.

### IV. Analysis of Final Rules

#### A. The General Rule Against Physician Self-Referrals

The prohibition against physician self-referrals is stated in the final rules as follows:

[A] physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or
A physician’s prohibited relationship with an entity will not automatically be imputed to other members of the physician’s group practice; however, a referral from the physician’s group practice, its members, or its staff will be imputed to the physician if such referrals are controlled by the physician.

The final rule also states that such entities may not present a Medicare claim for such prohibited services; that Medicare payment may not be made for such services; and that any entity collecting such a Medicare reimbursement must refund any amounts mistakenly collected in violation of the rules. However, payment for DHS may be made to an entity that receives a prohibited referral if the entity did not have actual knowledge, and did not act in reckless disregard or deliberate ignorance, of the identity of the physician who made the referral, and the claim complies with all other applicable federal laws, rules, and regulations. As noted above, the entity to which a referral is made for DHS has a duty of reasonable inquiry with respect to the existence of a financial relationship.

Note that services that are not covered by Medicare are not subject to these rules.

B. Definitions and General Provisions

1. Who is covered by the rules? The final rules apply to all physicians, as defined by the Medicare Act, for referrals for services and items to entities in which the physician, or his or her immediate family member, has a financial interest or compensation arrangement.

The Medicare Act defines a **physician** to include M.D.s, D.O.s, optometrists, podiatrists, doctors of dental surgery or dental medicine, and chiropractors.

An **immediate family member** means a spouse, a child, a birth or adoptive parent, a sibling, a grandparent or grandchild, the spouse of a grandparent or grandchild, including a stepparent, stepchild, stepsibling, parent-in-law, sibling-in-law, and child-in-law. Although this summary refers primarily to the physician’s financial interest or compensation arrangement, the rules apply to situations in which an immediate family member has a financial relationship as well.

2. What is a “financial relationship?” A financial relationship may be a direct or indirect ownership interest or compensation arrangement. Ownership interests include equity, secured loans, partnership shares, limited liability company memberships, stock options, bonds, and other financial instruments, but not retirement plan interests, unexercised stock options, subordinated unsecured loans, and “under arrangements” contracts between hospitals and physicians. Note that an ownership or investment interest that meets a general or ownership exception does not also have to meet a compensation exception with respect to profit distributions, dividends, interest payments on secured obligations, or other investment income.

The final rules specify that **indirect ownership interests** qualify as financial relationships as long as there is (i) an unbroken chain of any number of persons or entities between the referring physician and the DHS entity with linked ownership or investment interests between them, and (ii) the entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician has some direct or indirect ownership or investment interest in the DHS entity. Thus, an ownership interest includes an investment in an entity that holds an ownership interest in an entity that provides a designated health service. However, an interest in a subsidiary is not an interest in the parent of an organization or its affiliated entities unless the subsidiary holds an interest in the parent or affiliate.

A **compensation arrangement** is defined as “any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician’s immediate family) and an entity.” The rules elaborate on some of the exceptions that are not considered to be compensation arrangements under the statute. Other exceptions will be covered in Phase II.

The final rule defines **indirect compensation arrangement** as (i) an unbroken chain of any number of persons or entities between the referring physician and the entity furnishing DHS with linked financial relationships (i.e., either ownership or compensation) between them; (ii) the referring physician receives aggregate compensation from the next link in the compensation chain that varies with, or otherwise reflects, the volume or value of referrals or other
business generated by the referring physician for the entity furnishing DHS; and (iii) the entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with the volume or value or other business generated by the physician for the entity furnishing DHS. If the financial relationship between the physician and the next person or entity in the chain of relationships is an ownership interest, HCFA will look at the aggregate compensation between the next compensation link in the financial relationships chain that is closest to the referring physician to determine whether that compensation varies with the volume or value of referrals or other business generated by the referring physician.

These definitions of indirect ownership and compensation are very confusing and will almost certainly create compliance problems for physicians and the entities with which they have financial relationships.

3. Special Compensation Rules. Several of the compensation exceptions require that compensation be set in advance and not be related to the volume or value of referrals or other business generated between the referring physician and the entity furnishing DHS. Compensation will be deemed not to take into account the volume or value of referrals or other business if the compensation is consistent with the fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account DHS referrals or other federal or private pay business between the parties.

The final rules clarify that compensation can meet these requirements if it is time-based or based on a per use or per service basis, as long as these fees (i) are at fair market value for the items or services provided; (ii) do not include any additional amount attributable to the volume or value of referrals or other business generated between the parties (whether federal or private pay); and (iii) do not vary during the term of the compensation agreement in any manner that takes into account referrals to the DHS entity. However, percentage-based compensation will not be deemed to be set in advance if the percentage compensation is based on fluctuating or indeterminate measures (i.e., percent of revenues, collections, expenses) or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser. On the other hand, a percentage arrangement based on a fixed measure, such as an unfluctuating fee schedule, would be permissible. The final rules caution that per use or per service arrangements, as well as percentage arrangements, could violate the federal antikickback statute even if they are permitted under Stark II.

In determining fair market value, HCFA will generally look to the price the entity furnishing DHS would pay for the item or service in an arms-length transaction with another party that did not have any physician ownership or investment with the entity furnishing DHS. In some cases, the agency will look to alternative valuation methodologies, including, but not limited to cost plus reasonable rate of return on investment. The key is that the compensation should not be inflated to reflect the potential for referrals from the physician to the entity furnishing DHS.

Lastly, a physician may be required to make DHS referrals to a particular entity as a condition of payment as long as (i) the compensation arrangement meets the requirements discussed above and complies with an applicable exception; (ii) the referral requirement is in writing; and (iii) the requirement does not apply if the patient expresses a preference for a different DHS provider, practitioner, or supplier; the patient’s insurer specifies a different provider; or the referral is not in the patient’s best interests in the physician’s judgment.

4. What constitutes “remuneration?” Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. The final rules specifically exclude certain arrangements from the definition of remuneration, including the forgiveness of amounts owed for inaccurate or mistakenly performed procedures or tests or for minor billing errors. Moreover, certain items, such as those used solely for transportation, collection, processing, or storage of specimens for the entity, or that are used solely to order or communicate the results of tests or procedures for the entity, are not considered to be remuneration. Insurance reimbursements are also not treated as remuneration as long as certain conditions are met.

5. What constitutes a “referral?” A referral may be either a request for any DHS covered by Medicare, including consultations and the tests or procedures performed by the consulting physician, or a plan of care by a physician that includes any designated health service covered by Medicare. The statute and the rules exempt certain categories from what would otherwise constitute a referral, such as clinical diagnostic laboratory tests and examination services requested by pathologists;
diagnostic radiology services requested by radiologists; and radiation therapy requested by radiation oncologists, as long as the request arises from a consultation initiated by another physician, and those services are performed by or under the supervision of the pathologist, radiologist, or radiation oncologist. These exceptions do not apply if the referring physician knows or has reason to suspect that the consultant will order DHS from an entity with which the referring physician has a financial relationship to which no exception applies. Likewise, the exception does not apply if the provider furnishing DHS knows or has reason to suspect that the initial referral came from a prohibited source.

The proposed rule clarifies that the statute only applies to referrals of DHS and does not preclude referrals of other Medicare services, including physician services not specifically identified as DHS.

In one of the most significant changes from the proposed rules, **HCFA has decided that a covered referral does not include DHS personally performed by the referring physician.** However, a DHS is not personally performed or provided by the referring physician if it is performed by another person, including the physician’s employees, independent contractors, or group practice members. While an improvement over the proposed rules, which would have treated DHS personally performed by the referring physician as a covered referral, the final rule is still out of step with the HHS Office of Inspector General’s interpretation that the Medicare-Medicaid antikickback law does not cover any referrals within a single entity or between one entity and a wholly-owned subsidiary.

Stark II applies only to program referrals by physicians **to an entity** with which the physician has a financial relationship. Therefore, if the physician does not specifically refer the patient to a particular entity, the referral prohibition should not apply. On this score, the final rules create an exception for indirect and oral referrals. When there is no written order or other documentation for the referral, HCFA will look to see whether the provider furnishing DHS knew or had reason to suspect the identity of the physician who made the referral for DHS.

The physician is responsible only for his or her own referrals, not those of other members of a group practice. So if one member of a group practice is prohibited from referring to a particular entity because he or she has a financial relationship with that entity, the other members of the group are not precluded from making such referrals, unless they also have a direct or indirect financial relationship with the entity. However, if the physician-owners in the group have the power to influence or control the referrals of the non-owner physicians in the group and actual referral patterns reveal a scheme to circumvent Stark II (e.g., through a cross-referral arrangement), then the referral prohibition could still apply. Indeed, the statute provides enhanced penalties for such circumvention schemes.

6. **What is an “entity?”** The final rules clarify that Stark II applies only to referrals to entities that “furnish” DHS. An entity can be a physician’s solo practice or a group practice, or any other person, sole proprietorship, trust, corporation, partnership, limited liability company, foundation, or other organizational structure. The term includes sole proprietorships of physicians and group or joint practices of physicians. Consistent with its definition of “referral,” HCFA clarifies that an entity does not include the referring physician, but does include his or her medical practice. A person or entity is considered to be furnishing DHS only if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient’s behalf. **This means that, in most cases, drug and medical device manufacturers are not entities that furnish DHS. Therefore, the ordering, dispensing, or prescribing of drugs would not constitute a referral to the manufacturer covered by Stark II.**

7. **What are “designated health services?”** Stark II only applies to referrals of DHS covered by Medicare. Under the final rules, DHS for clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services, and radiation therapy services will be determined solely by reference to a list of CPT and HCPSC codes published with the final rule. HCFA will update this list at least annually, and has indicated that it will post the most current list on its web site. All other designated health services will be determined by a combination of CPT and HCPSC codes and other factors. The final rule includes specific definitions for these other services.

The final rule clarifies that DHS for “outpatient prescription drugs” includes all prescription drugs covered by Medicare Part B. However, HCFA maintains that the broadening of its definitions of group practice and referral and the direct supervision requirement of the in-office ancillary services exception, as well as the new exception for EPO (erythropoietin) and dialysis-related
outpatient prescription drugs, should generally permit physicians to administer or dispense drugs to patients in their offices without substantial risk of Stark II liability. The rule further clarifies that physicians are not required to pass on to Medicare discounts they receive in purchasing these drugs, unless otherwise required to do so by the Medicare program.

8. What is not a “designated health service?” The final rules exclude services that are reimbursed by Medicare as part of a composite rate (e.g., ASC services or skilled nursing facility Part A payments), except to the extent the DHS is itself payable through a composite rate (e.g., inpatient and outpatient hospital services). Physicians who perform surgery in an ASC in which they have an ownership interest will be pleased to learn that any DHS included in the ASC composite rate will not be subject to Stark II. Most physician services are not DHS.

At the same time, the agency proposes to exclude all invasive radiology procedures—imaging modalities used to guide a needle, probe, or catheter—as well as radiology procedures performed during and as an integral part of a nonradiological medical procedure, and all nuclear medicine procedures. The final rule also excludes screening mammographies, pap smears, and certain other diagnostic tests from the list of radiology codes included as DHS.

9. What is a “group practice?” The definition of “group practice” is important for meeting the in-office ancillary services exception described below. In order to qualify as a “group practice” under Stark II, the following conditions must be met:

- A group must be organized into a single legal entity (e.g., a partnership, corporation, limited liability company, faculty practice plan, or similar association) formed primarily for the purpose of being a medical practice; a group that merely holds itself out as such does not meet the statutory definition. However, individuals who are separately incorporated as individual professional corporations can still qualify as members of a group. A group practice can be owned by another corporation, as long as that entity does not also practice medicine. The group may own other entities.

- The practice must have two or more physicians, whether employees or direct or indirect owners. A practice with one physician owner and one physician employee (who are not the same person) would meet this requirement.

- Each member of the group must furnish substantially the full range of patient care services routinely furnished by the physician, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, personnel, and equipment.

- At least 75 percent of the total patient care services of the group members must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. The final rules require group practices to make a good faith effort to comply with this provision no later than 12 months after formation of the practice.

- The members of the group must personally conduct at least 75 percent of the physician-patient encounters of the group.

- Overhead expenses and income from the practice must be distributed according to methods determined prior to receipt of payment for the services giving rise to the overhead expense or producing the income. The practice must also be a unified business with some form of centralized decision making process, consolidated billing, accounting, financial reporting, and centralized utilization review.

- No member of the group practice may receive (directly or indirectly) compensation based on the volume or value of Medicare referrals for DHS. However, productivity bonuses based on overall profits from DHS, or DHS performed personally by the physician (or incident to that physician’s services) are allowed, so long as these bonuses are unrelated to volume or value of Medicare referrals of DHS. The rule provides several examples of methods of dividing profits or other circumstances that would meet this requirement (e.g. per capita or based on same distribution of profits as attributed to non-DHS services payable by federal health care programs).

Members of the group include physician owners and employees, as well as locum tenens physicians or an on-call physician while the physician is providing on-call services. Like the proposed rule, the final rule states that independent contractors may not be treated as members...
of a group practice. The agency decided that including independent contractors would make it more difficult for practices to meet the “75 percent of patient care services” test discussed above. However, unlike the proposed rule, the final rule says that independent contractors will be considered to be “physicians in the group” who can supervise physicians under the ancillary services exception (described below) if they have a contractual arrangement to provide services to the group’s patients in the group’s facilities and the arrangement complies with the Medicare reassignment rules. Independent contractors may also receive overall profit shares and productivity bonuses consistent with the requirements discussed above.

In another significant departure from the proposed rules, the final rules eliminate the group practice attestation requirement. This rule would have forced group practices to submit a written statement to their Medicare carriers each year attesting to their compliance with the criteria for meeting the group practice definition.

C. Exceptions

Stark II covers three categories of exceptions: those that apply both to ownership and compensation relationships, those that apply only to ownership interests, and those that apply only to compensation arrangements. Phase I includes exceptions that apply to both ownership and compensation arrangements or just to compensation arrangements. The final rules offer several new exceptions in these categories based on HCFA’s authority to exempt activities that do not raise a substantial risk of patient or program abuse. The remaining exceptions will be covered by Phase II.

1. Exceptions Related to Both Ownership and Compensation

a. Physician Services

The few physician services that are treated as DHS (e.g., the professional component of radiology services) are exempted from the Stark II rules as long as such services are furnished by (or supervised personally by) another physician in the referring physician’s same group practice. Such services are those that “can only be performed by a physician.” In other words, this exception applies only where the referral is to another member of the same group practice or an independent contractor of the practice, or provided by someone else who is personally supervised by a member or independent contractor of the group practice. The supervision standard here is the one that applies for that service under the Medicare coverage rules. This exception applies to “incident to” services only if those services are physician services. Otherwise, the “incident to” services must meet another exception.

b. In-office Ancillary Services

One of the most important and controversial exceptions to the Stark law is the in-office ancillary services exception, which protects revenues earned from most DHS provided within a solo or group practice if certain conditions relating to the identity of the person providing the service, the location of the service, and the identity of the entity billing for the service are followed. The self-referral prohibition does not apply to “in-office ancillary services” if they are:

- furnished personally by the referring physician (either in a solo or group practice), by another physician who is a member of the referring physician’s group practice, or by individuals who are supervised by the referring physician or another physician in the same group practice as the referring physician (i.e., another member or an independent contractor of the group practice, as long as the supervision complies with all other applicable Medicare payment and coverage rules for the physician services);

- furnished in (a) the same building (i.e., same physical structure or group of structures with a common address, but not necessarily the same space or part of the building) in which the referring physician (or another physician who is a member of the same group practice) furnishes substantial physician services unrelated to the furnishing of DHS, where such unrelated services represent substantially the full range of physician non-DHS services that the referring physician routinely provides, and the receipt of DHS is not the primary reason the patient comes in contact with the referring physician or his or her group practice; or (b) furnished in another building that is used by the group practice for the centralized provision of the group’s clinical laboratory services or other DHS; and

- billed by (a) the physician performing or supervising the service, (b) the group practice of which that physician is a member or independent contractor under a billing number assigned to the group
practice, (c) an entity that is wholly owned by the performing or supervising physician or that physician’s group practice under a billing number assigned to the physician or group practice; or (d) an independent billing agent of the referring physician, group practice, or other entity permitted to bill under this exception. Group practices may bill under more than one Medicare billing number.

As noted above, the final rule states that, for purposes of this exception, independent contractors are not included as members of the group practice, but are now treated as “physicians in the group” who can supervise the provision of DHS. The proposed rules set forth a very restrictive supervision standard, which would have required the supervising physician to be “present in the office suite in which the services are being furnished throughout the time they are being furnished, and immediately available to provide assistance and direction.” The final rule merely requires the services to be provided in accordance with the existing supervision standards under the applicable Medicare coverage and payment rules, such as the supervision standards for diagnostic tests.

The final rules also state that DHS services provided under the “same building” option may be provided in a shared facility—i.e., a shared x-ray suite or laboratory. However, mobile units, vans, trailers, and exterior spaces do not satisfy the same building requirement, although an SNF or patient’s home could qualify if that is where the physician regularly provides his or her services, and the physician provides non-DHS services during the same visit. Centralized facilities mean all or part of a building, including mobile units, vans, and trailers, that are used exclusively by the group on a 24/7 basis for a term of not less than six months. Shared facilities do not qualify. A group practice may have more than one centralized facility.

The in-office ancillary services exception covers all DHS except parenteral and enteral nutrients, equipment, and supplies, and most DME. The final rule expands the list of eligible DME to include crutches, canes, walkers, folding manual wheelchairs, and DME infusion pumps, to the extent they are necessary for the patient to safely leave the physician’s office. The exception also covers blood glucose monitors that are furnished by a physician or employee of a physician or group practice that furnishes outpatient diabetes self-management training to the patient. These services must be provided in the same building in which the physician’s or group practice’s office is located (i.e., not in a building used for the centralized delivery of DHS), meet all of the other requirements for the in-office ancillary services exception and DME supplier standards, and not violate the Medicare-Medicaid antikickback law.

c. Implants in an ASC (new)

Implants furnished in an ASC, including cochlear implants, intraocular lens, prosthetics, prosthetic devices, and DME, are exempt from Stark if the following conditions are met:

- The implant is furnished by the referring physician or a member of the referring physician’s group practice in a Medicare-certified ASC with which the referring physician has a financial relationship.
- The implant is inserted in the patient during a surgical procedure performed in the same ASC where the implant is furnished.
- The arrangement for furnishing the implant does not violate the federal antikickback statute, and the billing and claims submissions for the implant comply with all federal and state laws and regulations.

This implant exception applies only to the physician’s financial relationship with the ASC.

d. Prepaid Health Plans

Stark II has a specific exception for services provided by Medicare + Choice plans, HMOs, certain other health care prepayment plans under contract with Medicare, and organizations participating in prepaid Medicare managed
care demonstration projects. The final rules clarify that this exception will also protect DHS referrals by downstream providers that have contracts with the covered organizations, as well as their subcontractors, for services they furnish to enrollees of these organizations. HCFA has also revised the definition of entity to permit physician ownership of network-type HMOs, MCOs, provider-sponsored organizations (“PSOs”) and independent practice associations (“IPAs”). Physician referrals to such organizations in which they have an ownership interest would not be covered by Stark II unless the organization furnishes DHS through an employee or operates a facility that can accept payment directly or indirectly from Medicare, or employs a supplier or accepts reassignment from a supplier. The inclusion of Medicaid managed care plans under this exception will be addressed in Phase II of the rulemaking.

e. Post-Cataract Eyewear (new)

The final rules create an exception for eyeglasses and contact lenses furnished after cataract surgery if the following conditions are met:

- The eyewear is provided in accordance with the applicable Medicare coverage and payment rules;
- The arrangement for furnishing the eyewear does not violate the federal antikickback law, and billing and claims submission for the eyewear comply with all federal and state laws and regulations.
- The effect of this exception is to permit ophthalmologists to refer Medicare patients to optical shops in which they have ownership interests without triggering any Stark II scrutiny. However, these referrals still need to comply with the federal antikickback statute.

f. Academic Medical Centers (new)

The final rules create a new exception for services provided by an academic medical center (“AMC”). An AMC is defined to include an accredited medical school, a tax-exempt affiliated faculty practice plan, or one or more affiliated hospitals in which a majority of the medical staff consists of physicians who are faculty members and most of the hospital admissions are made by physician faculty members. To qualify for this exception, the AMC must meet the following conditions:

- The referring physician is a bona fide employee of a component of the AMC on a full-time or substantial part-time basis, is licensed to practice medicine in the state, has a bona fide faculty appointment at the affiliated medical school, and provides substantial academic or clinical teaching services for which he or she is compensated as part of his or her employment relationship with the AMC.
- The total compensation paid for the previous 12-month period (or fiscal or calendar year) from all AMC components to the referring physician is set in advance and does not exceed fair market value for the services provided, does not take into account the volume or value of referrals from the physician, and does not violate the federal antikickback law.
- All transfers of money between components of the AMC must support the missions of teaching, indigent care, research, or community service.
- The relationship between the components of the AMC must be set forth in an agreement adopted by the AMC governing body for each component.
- All funds paid to the referring physician for research must be used solely for bona fide research.

Consistent with the general compensation rules described above, compensation programs based on a percentage of fees collected likely do not meet the “set in advance standard” for faculty compensation. This may require significant changes in existing faculty compensation arrangements, many of which are based on percentage-based division of revenues.

2. Exceptions for Compensation Arrangements

a. Fair Market Value Compensation (new)

The self-referral prohibition does not apply to compensation arrangements between an entity and a physician or any group of physicians (regardless of whether the group meets the definition of a group practice) for the provision of items or services by the physician or group practice to the entity if the arrangement is set forth in an agreement that meets the following conditions:

- It is in writing, signed by the parties, and covers only identifiable items or services, which are specified in the agreement.
It specifies the time frame for the arrangement, which can be for any period of time and can contain termination clauses if the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement for less than one year can be renewed an indefinite number of times if the terms and compensation for the same items or services do not change.

- The compensation must be set in advance, be consistent with fair market value, and not be tied to the volume or value of any referrals or other business generated between the parties. Per use or per service payments are permitted; percentage compensation arrangements are not.

- The transaction is commercially reasonable and furthers the legitimate business purposes of the parties.

- The arrangement meets a safe harbor under the federal antikickback statute, has been approved by the OIG under a favorable advisory opinion, or does not violate the antikickback statute. In addition, the services to be performed under the arrangement do not involve the counseling and promotion of a business arrangement or other activity that violates federal or state law.

The final rules define “fair market value” to mean:

The value in arms-length transactions, consistent with the general market value. “General market value” means the price that asset would bring, as a result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement, as a result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition or at the time of the service agreement.

As noted above, in some cases where there are no comparables, HCFA will consider alternative methods of determining fair market value, including cost plus reasonable rate of return. The fair market value exception promises to provide physicians and entities furnishing DHS with much greater flexibility in avoiding Stark liability in cases where financial arrangements cannot be fit within another compensation exception.

b. Non-monetary Compensation
Up to $300

The final rules create an exception for non-monetary compensation paid to a referring physician that does not exceed an aggregate of $300 per year. This exception is modified from the de minimis exception in the proposed rules. The criteria for this exception are as follows:

- The compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.

- The compensation is not solicited by the referring physician or the physician’s practice, including employees and staff.

- The compensation does not violate the federal antikickback law.

Drug samples, training, and other gifts by laboratories or other entities furnishing covered DHS would generally be permitted under this exception. Note that this exception applies only to gifts to individual physicians, not group practices. Note also that HCFA considered but declined to create a professional courtesy exception at this time, but asked for comments on this issue.

c. Medical Staff Incidental Benefits (new)

Stark II does not apply to non-monetary compensation from a hospital to members of its medical staff based on items or services furnished on the hospital’s campus if the following conditions are met:

- The compensation is offered to all members of the medical staff without regard to the volume or value of referral or other business generated between the parties.

- The compensation is offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients.

- The compensation is provided by the hospital and used by the medical staff members only on the hospital campus.
The compensation is reasonably related to the provision of, or designed to facilitate the delivery of, medical services at the hospital.

The compensation is consistent with the types of benefits offered to medical staff members by other hospitals within the same locality or by comparable hospitals in comparable regions.

The compensation is of low value (i.e., less than $25) per occurrence, does not vary with the volume or value of referrals or other business generated between the parties, and does not violate the federal antikickback law.

This exception is intended to protect the incidental benefits, such as free parking, meals, and Internet access, provided by hospitals to members of the medical staff while treating hospital patients or providing services to the hospital.

d. Risk Sharing Arrangements (new)

Risk-sharing arrangements, including withhold, bonuses, and risk pools, between referring physicians and MCOs and IPAs are not covered by the self-referral law for services provided to enrollees of a health plan if the arrangement does not violate the federal antikickback law, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission.

e. Indirect Compensation Arrangements (new)

Indirect compensation arrangements are exempt from the self-referral prohibition if:

- The compensation received by the referring physician is consistent with the fair market value for the services covered by the arrangement for items and services actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician for the entity providing the DHS.

- The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship, in which case the arrangement need not be in writing, but must be for an identifiable service and be commercially reasonable even if no referrals are made to the employer.

- The compensation arrangement does not violate the federal antikickback statute or any laws relating to billing or claims submission.

f. Preventive Screening Tests, Immunizations, Vaccines (new)

The final rules exclude preventive screening tests, immunizations, and vaccines that are covered by Medicare and identified by the CPT and HCPCS codes on HCFA’s web site and annual updates if the tests, immunizations, and vaccines are subject to the HCFA-mandated frequency limits and are reimbursable under the Medicare fee schedule, and the arrangements for the provision of these tests do not violate the federal antikickback law and are otherwise lawful.

g. Other Exceptions

The final rule also establishes exceptions for:

- compliance training provided by hospitals to referring physicians;

- clinical lab services furnished in an ASC or ESRD, or by a hospice; and

- EPO and dialysis-related outpatient prescription drugs.

V. Conclusion

Phase I of the final Stark II rules contains many changes that should be helpful to physicians and entities that furnish DHS in their efforts to comply with this law.

However, the final rules are still enormously detailed and complex, creating many traps for the unwary. Physicians and DHS providers should take care to consult with experienced legal counsel before entering into any business or professional arrangements that implicate the statute.
Jenner & Block, LLC Health Law Briefs provides information on recent developments and general topics of interest in the field of health care law. Due to space limitations and the general nature of its contents, it should not be regarded as legal advice.

The Health Law Practice Group of Jenner & Block, LLC would be pleased to answer any questions of general interest to the health care community in future editions of Health Law Briefs. Please address any questions, or any comments about the report, to Rob Portman at (202) 639-6000 or rportman@jenner.com.

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