

Client Alert

A report for clients and friends of the firm

February 2001

Stark Law Final Regulations: Phase I

On January 4, 2001, HCFA published the first phase of final regulations implementing the Stark II Law. The regulations make important changes to the proposed regulations, and may require modifications to certain longstanding compensation structures and business relationships. This Client Alert summarizes these key changes, as well as other noteworthy features of the new regulations

Introduction

On January 4, 2001, the Health Care Financing Administration of the United States Department of Health and Human Services (HCFA) at last issued final regulations with respect to the Stark II Law (Social Security Act § 1877; 42 USC 1395nn). The rules fill 110 pages of the Federal Register (66 Fed. Reg. 856), but are only the first part of a two-stage process. HCFA calls these regulations "Phase I," and notes that "Phase II" will follow, but doesn't say when.

These Phase I rules cover important ground. The regulations address Stark Law basics, such as the general prohibition against billing for "self referred" services, and the definition of what counts as Stark-covered "designated health services." The regulations also deal with those Stark Law exceptions that can cover either ownership or compensation relationships, such as the "in-office ancillary services" exception, which is crucial to many group practice arrangements. Certain significant compensation relationship exceptions are also covered. The rules finalize the proposed "fair market value" compensation exception, and also add new compensation exceptions, such as for medical staff incidental benefits and for certain indirect compensation relationships. Phase II will address, among other issues, reporting requirements and sanctions, the remaining compensation exceptions, all ownership relationship exceptions, and the application of the Stark Law to Medicaid.

The Phase I regulations generally reflect a considered attempt to balance the need to enforce the Stark Law with the desire

to respect longstanding community practices. For example, physician group practices will benefit from the regulations' liberalization of the rules regarding the supervision of technicians within a group practice, as well as from the rules' greater latitude with respect to the definition of a group practice, and the manner in which group profits may be distributed. Others in the health industry, such as hospitals, will find a number of reasonable and workable new Stark Law exceptions that should serve to facilitate how business is conducted with referring physicians. However, the regulations will also necessitate a careful review of many existing relationships, particularly regarding office leasing arrangements.

To avoid upsetting existing relationships, the effective date of the Phase I regulations is January 4, 2002. The sole exception is a provision requiring that physicians who prepare medical necessity certifications for home health care agencies have Stark-compliant financial relationships with those agencies. That provision was originally scheduled to take effect February 5, 2001, but this date has been postponed for at least 60 days (to April 6) in order to permit the Bush administration to review the regulation. HCFA has also solicited comments on the Phase I regulations, which must be submitted by April 4, 2001.

What follows is a discussion of highlights from the Phase I regulations. The discussion begins with the regulatory treatment of the key Stark Law concepts of "designated health services," "referrals," "compensation," "ownership" and "indirect financial relationship." Special attention is given to important developments regarding HCFA's understanding of "indirect

compensation" under the Stark Law. The discussion then turns to rules of special importance to physician group practices. Provisions that will particularly affect hospitals are covered next, and then certain noteworthy new exceptions to the Stark Law prohibition. The discussion does not cover all aspects of the Phase I regulations, and health care providers with potential Stark Law issues should consult with counsel to assure compliance.

Key Stark Law Concepts

Designated Health Services. The regulations introduce a specific list of CPT codes to define a number of designated health services, including physical therapy, occupational therapy and clinical laboratory services. This bright line test is clearly preferable to the ambiguity inherent in earlier definitions of designated health services.

Referral. The regulations amend the definition of "referral" to exclude expressly a request for a designated health service personally performed by the referring physician. The service must be performed by the referring physician and it cannot be performed by any other person or entity (including the referring physician's employees, independent contractors or group practice members).

Compensation. The regulations clarify that the myriad Stark Law rules requiring that "compensation be set in advance" permit fair market value time-based or per-unit-of-service-based fees, even when paid to the referral source. However, HCFA has determined that percentage arrangements are *not* permissible as compensation that is set in advance. This is a new interpretation which may require modification to certain existing relationships.

In another substantial change to the proposed regulations, the Phase I regulations permit a physician's compensation to be conditioned on a physician making particular referrals. Specifically, a physician may be required to refer patients to a particular provider, practitioner or supplier if the compensation arrangement complies with an applicable exception and is set forth in writing. In addition, the requirement must be inapplicable in the event that a patient expresses a different preference, the patient's insurer determines the provider of the service, or if the referral is not in the patient's best medical interest in the physician's judgment.

Ownership and Investment Interests. "Ownership and investments" are defined to exclude stock options until such time as

the options are exercised, although stock options often will create a compensation relationship. In addition, debt that is secured is deemed to be an ownership interest. Interest in a retirement plan is not an ownership interest. Ownership or investment interest in a subsidiary company is not ownership in a parent or other subsidiary per se, unless the subsidiary has a ownership or investment interest in the parent or other affiliate.

Indirect Financial Relationships. The Phase I regulations devote considerable attention to "indirect" financial relationships between a referring physician and an entity that furnishes DHS. HCFA has attempted to craft clear, bright-line rules. The approach taken, however, raises serious questions, particularly regarding indirect compensation relationships. One main issue concerns the manner in which HCFA's definition of "indirect compensation interest" appears to take much of the force out of HCFA's proposed new regulatory exception for indirect compensation relationships. The other issue concerns the extent to which the indirect compensation concept, as a whole, seems to swallow up (perhaps inadvertently) other potential bases for Stark Law compliance.

The regulations define an indirect *ownership or investment* interest (the Indirect Ownership Definition) as including "an unbroken chain" of any number (but no fewer than one) of persons or entities having ownership or investment interests between them where the entity that submits a claim for DHS had actual knowledge of, or acted in deliberate disregard or deliberate ignorance of, the identity of the physician who made the DHS referral. The Indirect Ownership Definition appears to be relatively straightforward and easy to apply. If these criteria are not met, HCFA would not consider an indirect ownership or investment interest to exist between a referring physician and an entity that furnishes DHS, and thus no Stark Law issues would be raised by reason of any such relationship.

The definition of indirect *compensation* interest (the Indirect Compensation Definition) found in the Phase I regulations, however, is more complicated. Under the Phase I regulations, the Indirect Compensation Definition covers arrangements where the following exists: (1) there is an unbroken chain of investment, ownership or compensation relationships between the referring physician and the entity that furnishes DHS, (2) the compensation received by the referring physician from the person or entity in the chain with which the physician has a direct financial relationship varies with or otherwise reflects the volume of value or referrals or other business generated by the referring physician for the entity that furnishes DHS, and (3)

the entity that submits a claim for DHS had actual knowledge of, or acted in deliberate disregard or deliberate ignorance of, the identity of the physician who made the DHS referral. If these criteria are not met, HCFA would not consider an indirect compensation interest to exist between a referring physician and an entity that furnishes DHS, and thus no Stark Law issues would be raised by reason of any such relationship.

Notably, HCFA provides that with respect to both the Indirect Ownership Definition and the Indirect Compensation Definition, the entity that furnishes DHS has no generalized affirmative duty to inquire or investigate whether an indirect financial relationship with a referring physician (or immediate family member) exists, absent some information that would put a reasonable person on alert, and that the duty that is imposed is one of reasonable inquiry in the circumstances.

The Phase I regulatory provisions governing indirect compensation arrangements are further complicated by a new specific exception for indirect compensation arrangements (the Indirect Compensation Exception). The Indirect Compensation Exception recognizes and permits indirect compensation relationships so long as the compensation is fair market value, does not take into account the volume or value of referrals, is in writing (unless it is an employment agreement) that specifies the services covered by the arrangement, and does not otherwise violate the Anti-Kickback Law or other laws relating to billing or claim submission.

Unfortunately, the Indirect Compensation Definition and the Indirect Compensation Exception appear to be at odds with one another. As noted above, one criterion for the Indirect Compensation Definition is that the payment made by the intermediary entity to the referring physician vary with, or otherwise reflect, the volume or value of referrals or other business generated by the referring physician for the DHS entity. HCFA explains that the "volume or value" standard in this context includes any business, not just DHS, and also incorporates per unit or per service fees if those fees are tied to the DHS provider's volume (as they generally would be). Thus, if there is no such variation in the referring physician's compensation, there would be no indirect compensation relationship within the meaning of the Stark Law. However, as also noted above, one criterion for the Indirect Compensation Exception is that the compensation received by the referring physician not take into account the volume or value of referrals or other business generated by the referring physician for the DHS entity. Since the Indirect Compensation Definition appears to exclude from

the purview of the Stark Law arrangements that are *not* based on the volume or value of referrals, it is hard to imagine how the Indirect Compensation Exception could ever apply. In other words, there would never be a need to turn to the Indirect Compensation Exception because any indirect financial arrangement that meets its requirements would already have escaped Stark Law coverage under the Indirect Compensation Definition.

An answer to this conundrum may lie in HCFA's discussion of the "volume or value" standard as it is used in the Indirect Compensation Exception. As noted above, for purposes of the Indirect Compensation Definition, HCFA states its intent to treat per unit/per service as volume based. However, HCFA also notes that, for purposes of the Indirect Compensation Exception, *but not for purposes of the Indirect Compensation Definition*, it will treat per unit/per service fees as *not* volume based. In other words, per unit/per service fees would appear to be volume based for purposes of the Indirect Compensation Definition, but *not* volume based for purpose of the Indirect Compensation Exception, and thus are acceptable if the other requirements for the exception are met. This means that the Indirect Compensation Exception would seem to have meaning or relevance only for circumstances where there is a unit-based fee structure.

Given how often referring physicians are in indirect rather than direct compensation relationships with entities that furnish DHS, the inclusion of these new "bright line" indirect compensation rules would seem materially to shift current understandings of what is necessary in order to achieve Stark Law compliance. As noted above, if a referring physician's compensation does not vary based on the volume or value of his or her referrals to a DHS entity, the "volume or value" criterion of the Indirect Compensation Definition is not met, and Stark Law compliance is achieved. This suggests that if a DHS entity contracts not directly with a referring physician, but instead with a professional corporation or other entity owned by or in a compensation relationship with such referring physician (a Physician Entity), the first and often the only issue presented would be whether the compensation relationships at issue under the Indirect Compensation Definition are "volume based." (If the referring physician owns the Physician Entity, the compensation relationships at issue would generally be that between the DHS entity and the Physician Entity. If the referring physician does not own the Physician Entity, the compensation relationship at issue would generally be that between the Physician Entity and the referring physician.) It appears

that if the applicable compensation relationship is not volume based, no other Stark Law exception need even to be considered because the arrangement would fall outside of the Indirect Compensation Definition. Most compensation arrangements at issue under the Stark Law are not direct employment relationships with referring physicians, but instead will be between Physician Entities and entities that furnish DHS. It thus appears that the Indirect Compensation Definition's "volume based" criterion has subsumed most of the complex compensation relationship exception requirements — other than those related to W-2 employment — under the Stark Law.

Three caveats are in order. First, any deliberate effort to create a corporate intermediary to avoid the strictures of the Stark Law could be deemed a forbidden circumvention scheme. Second, if the arrangement is not fair market value or otherwise bona fide, it may be deemed to be based on the volume or value of referrals, even if it were not literally variable by volume. Third, it is also quite possible that HCFA did not intend the Indirect Compensation Definition to be so significant, and it may well be modified in the future.

Physician Group Practices

Members of the Group. HCFA has maintained the definition of "member of the group" for purposes of the group practice exception as including only owners (direct or indirect) and employees (including for this purpose locum tenens or on-call physicians, but excluding leased employees and independent contractors). HCFA has also resolved many of the problems inherent in this definition of "member of the group" by modifying the supervision requirement for the in-office ancillary service exception to permit supervision by independent contractors and the development of a new category of "physicians in the group practice," who may receive compensation based on productivity even though not "a member of the group." HCFA notes, however, that any physician who is an independent contractor with a group must comply with the Medicare reassignment rules which effectively preclude the group's billing for the physician's services at locations other than the group's offices (e.g., for services at a hospital).

Group Practice. The in-office ancillary services exception looms large in the Stark Law. It functions as the key exception that excludes from the Stark Law prohibition those designated health services referred to, and provided by, other members of a group practice. However, in order to take advantage of this exception, a physician practice must meet the detailed Stark

Law requirements of a "group practice." The Phase I regulations address the "group practice" definition in a number of ways. First, they retain from the proposed regulations the "single entity" concept as a basis for the definition of a group practice. The single entity may not be organized or owned in whole or in part by another active medical practice — although, in a change from the proposed regulation, it may be owned by any type or number of entities, as long as the owning entities do not include an operating physician practice. Although the group may be formed by any individual or entity, and does not require physician ownership, it must have two or more physician "members" who may be employees, direct owners or indirect owners. Also, the preamble to the Phase I regulations makes clear that the entity must be organized for purposes of operating a physician group practice. It also makes clear that an entire hospital entity cannot be a group practice.

The Phase I regulations also retain, with insignificant alteration, the proposed regulations' requirements that: (1) each member of the group (which excludes contractors) furnish for the group the full range of patient care services that they routinely provide; (2) 75% of the total patient care services provided by members of the group be provided through, and billed by, the group; and (3) 75% of the group's patient encounters (measured per capita, not by time) must be conducted by members of the group. However, the Phase I regulations permit groups some flexibility in determining how to measure the 75% requirement, and a new entity is given a reasonable opportunity to establish that it complies.

The Phase I regulations modify and substantially soften the proposed regulation that would have required the group to be operated as a unified business. Under the regulations, the group must have the following features: (1) centralized decision making by a body representative of the group that maintains effective control over the group's assets and liabilities (budgets, compensation and salaries); (2) consolidated billing, accounting and financial reporting; and (3) centralized utilization review. The proposed regulation's prohibition on treating separate offices as separate profit centers is not included in the Phase I regulations. Revenue, overhead and expenses must be allocated in accordance with formulas that are in place prior to the receipt of payment for the services, and such a formula may be revised on a prospective basis only.

Importantly, HCFA has eliminated the problematic prohibition against payment to a physician of a productivity bonus based

on work personally performed by the physician, including designated health services. The Phase I regulations still prohibit, however, payment of productivity bonuses for services performed by other members of the group based on their the physician's referrals. Although there could be some ambiguity as to whether the Phase I regulations would permit a productivity bonus based on referrals for services that involve both a professional and technical component (with a physician providing professional service and supervising the technical component), it appears that the physician's productivity bonus may be based on the entire fee received by the group for the service. The definition of a referral excludes a referral by the physician to himself for a professional service he will perform. Under these circumstances, the only "referral" at issue under the Stark Law would be the technical component, and it would appear that the technical component reimbursement may be subject to a productivity bonus to the physician where the physician personally supervises the service. It should be noted that, although there is no statement that the productivity payments are limited to the professional component, the preamble also does not contain a statement that the productivity payments are limited to the technical component. (Note that there are clear statements that the reimbursement of hospitals and skilled nursing facilities for technical component services (e.g., the DRG payment) may not be the basis for a productivity bonus.)

Under the Phase I regulations, a productivity bonus for personally performed services would be deemed not to relate to the volume of referrals if the bonus: (1) is tied to total patient encounters or RVUs of each physician; (2) is based on the distribution of group practice revenues attributable to non-designated health services payable by any federal health care program or private payor; (3) includes designated health services revenues, provided that the revenues derived from designated health services constitute less than 5% of the group practice total revenues and the allocated amount of those revenues to each physician totals 5% or less of his or her total compensation from the group; or (4) is calculated in any reasonable manner not directly related to the volume or value of referrals of designated health services. It is important to note that the bonus could include group compensation resulting from the personal referrals of the physician providing the service as long as the distribution accords with one of the foregoing four standards. Group practices are required to maintain records adequate to verify the methods used for bonus determinations and profit allocations and the amounts of bonus payments and other compensation.

While the Phase I regulations retain the long standing approval of payments to a share of the overall profits of the group, they also expressly states that "overall profits" includes not only the profits of the entire group but the profits of any component of the group containing at least five physicians. The distribution is deemed not to relate to the volume of referrals if the group's profits are divided per capita or satisfy one of the methodologies in the preceding paragraph.

In addition, the Phase I regulations have deleted a proposal that groups submit annually to HCFA an attestation of compliance with group practice requirements.

Notably, the Phase I regulations also indicate that a physician's relationship with an individual or entity who is not part of the physician's group practice would not necessarily be imputed to his or her group practice members or staff unless certain facts or circumstances existed. For example, referrals by these outside parties may be imputed if the physician directs the individual or entity to make the referrals, or if the physician otherwise controls such referrals. This is a facts and circumstances test.

The In-Office Ancillary Services Exception

The Phase I regulations significantly modify the in-office ancillary services exception:

- *Supervision.* First, an important liberalization from the proposed regulations pertains to the supervision required for a designated health service in the group practice context. In an effort to simplify the requirements, the Phase I regulations utilize the requirements of the Medicare coverage rules, and now permit independent contractors to supervise technical services.
- *Location.* The services must be furnished in one of two locations: (1) the same building (newly defined as a single street address assigned by the United States Postal Service) in which the referring physician or another physician in the same group practice furnishes substantial physician services (which must represent substantially the full range of physician services unrelated to the furnishing of designated health services that the referring physician routinely provides (or, in the case of the physician who is a member of a group practice, that such physician provides for the group practice)) that are unrelated to designated health services that are payable by a federal health care program or private payor, or (2) a centralized building, as

further described below. Finally, the receipt of the designated health service cannot be the primary reason the patient comes into contact with the referring physician of his or her group practice.

- *Centralized DHS Buildings.* In addition, the location for designated health services for a group practice can include a central building for clinical laboratory services and for some or all of the group practice's other designated health services. Notably, the centralized building definition is now very limited and excludes part-time arrangements. The definition requires that the centralized building be owned or leased by the group on a full-time basis (24 hours/7 days a week) for at least six months. This prohibition on part-time relationships may have a significant impact on, and require revision of, transactions whereby designated health services providers (e.g., radiology practices) leased their facilities to referring physicians. In addition, a mobile vehicle and a trailer may only be used as a centralized building for group practices and will not be deemed to meet the same building requirement for solo practitioners.
- *Shared Facilities.* The definition of in-office ancillary services is also now amended to permit shared facilities that meet the other requirements for the exception.
- *DME.* The Phase I regulations now permit the issuance of certain durable medical equipment from the physician's office, namely, canes, crutches, walkers and folding manual wheelchairs, to the extent such DME is required to ambulate out of the office, and blood glucose monitors to begin blood glucose monitoring. The designated health services are deemed furnished for purposes of the ancillary service exception "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 the applicable Medicare payment and coverage rules."
- *Home Health Care Physicians.* A new rule protects as in-office ancillary services those services rendered in a patient's home by a referring physician or staff accompanying the physician where the physician's "principal medical practice consists of treating patients in their private homes."
- *Billing.* Finally, in-office ancillary services must, as under the proposed rule, be billed by the physician performing the service, or the group.

Hospitals

Academic Medical Centers. The Phase I regulations contain a new exception for academic medical centers which would apply to hospital relationships with physicians that are either in the form of compensation relationships or in the form of ownership or investment interests. The regulations define an academic medical center as an accredited medical school, a 501(c)(3) tax-exempt affiliate faculty practice plan, and "one or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members." This safe harbor applies if the referring physician is a bona fide employee on a full-time or substantial part-time basis of a component of the academic medical center (components include medical schools, faculty practice plans and hospitals, among other entities). The physician must be licensed in the state and have a bona fide faculty appointment, and provide substantial academic or substantial clinical teaching services for which the faculty member receives compensation. The total compensation paid from all academic medical center components must be set in advance and the aggregate may not exceed fair market value for the services provided and not take into account the volume or value of any referrals. As noted above, compensation which is set in advance does not include percentage of revenue transactions, although the "set in advance requirement" would allow unit of service payments.

In addition, the academic medical center must meet the following three requirements: (1) all transfers of money between the components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research or community service and the relationships between the components must be set in a writing that has been adopted by the governing body of each component (this may be a problem in cases where certain facilities have longstanding oral agreements that are not in fact reduced to writing); (2) all money paid to a referring physician for research must be used solely to support bona fide research; (3) and the compensation arrangement must not violate the Anti-Kickback Law.

This exception, although on its face of somewhat limited application, appears to reflect a broader and important view held by HCFA that academic medical centers must be seen as complex integrated organizations and that the application of the Stark Law and Anti-Kickback Law must reflect their integrated nature. Thus, transfers of money within components of an academic medical center are generally acceptable as long as the compensation pro-

vided to the physicians would meet the Stark Law exception for employment if such employment was by one of the components.

Office Leases With Physicians, and the Fair Market Value Requirement. The Phase I regulations have retained virtually all of the definition of fair market value from the proposed regulations through an interpretation contained in the preamble to the Phase I regulations. However, HCFA has completely modified a hospital's obligation in regard to its leases with physicians. In the case where a hospital is the lessor of space to a physician, HCFA notes:

We believe that it is fair to interpret the limitation in the fair market value definition as confined to situations in which a physician is the lessor and a potential source of referrals to an entity lessee. That limitation does not appear to us to apply when an entity, such as a hospital, is the lessor that rents space to physicians, even if the hospital is in a position to refer to the physicians. *As a result, we believe a hospital should factor in the value of proximity when charging rent to lessee physicians.* (emphasis added).

This remarkable quote turns the previous understanding of fair market value on its head. While commentators have been advising hospitals to do a counterintuitive thing in order to avoid a technical violation of the fair market value requirement—that is, they were advising hospitals to exclude the value of proximity to the hospital which would be payable on the open market by any potential lessee from their agreements with physicians—HCFA now appears specifically to require hospitals to take into account the additional value related to such proximity. This important change may require hospitals to review all of their lease agreements with physicians to determine whether they have been appropriately priced.

In the Phase I regulations, HCFA has focused its concern on inflated amounts paid to a physician to account for the proximity by an entity that will be receiving referrals from that physician. In the proposed regulations, the fair market value was based on use for general commercial purposes and did not include the intended use or proximity to a referral source of the property. A number of commentators noted that this would have the effect of actually devaluing property that in the open market would obtain a premium because of its location.

HCFA expressly permits consideration of the fair market value of "the area in which the property is located even if a lease is

for medical property in a 'medical community.'" Fair market value cannot include any additional value above that which is paid by other medical practitioners in the same building or in a similar location just because of the particular relationship between the lessor as a potential referral source for the lessee. In other words, and appropriately, "the rental payments should be roughly equivalent to those charged to similarly situated parties in arrangements in which referrals are not at issue."

Certain New Exceptions

Risk-Sharing Exception. A new general "risk-sharing" exception has been added to the pre-existing prepaid health services plan exception which has been limited to certain federally qualified entities. HCFA expressly recognizes that physicians are permitted to own an interest in "network-type" HMOs, managed care organizations, provider-sponsored organizations, or independent practice associations, unless they directly provide designated health services.

Special Billing Rate Services. The Phase I regulations include specific exceptions for laboratory services furnished in ambulatory surgical centers (ASC), end-stage renal disease (ESRD) facilities, or by a hospice. The services are included in the ASC rate, the ESRD composite rate or is part of the per diem hospice rate. A similar exception has been created for EPO and other dialysis related outpatient prescription drugs, which are identified pursuant to CPT and HCPCS codes, and implants provided in an ASC, although they are subject to the requirement that arrangements for the furnishing of these drugs and implants do not violate the Federal Act Kickback Law.

Preventive Screening. The Phase I regulations include exceptions for preventive screening tests, immunizations and vaccines that are subject to HCFA-mandated frequency limits, and eyeglass and contact lenses following cataract surgery that are provided in accordance with Medicare law.

Compliance Training and Non-Cash Medical Staff Benefits. A new exception protects compliance training provided by a hospital to a physician as well as incidental (non-cash) medical staff benefits that a hospital provides physicians. The benefits are protected only if the hospital offers the benefits without regard to the volume or value of referrals or other business generated by the physician, and the benefits are offered only during the periods when medical staff members are making rounds or performing other duties that benefit the hospital, the compensation is provided by the hospital and used by the med-

ical staff members only on the hospital's campus, and the compensation is reasonably related to the provision of, or designed to facilitate direct or indirect delivery of, medical services at the hospital, the compensation is consistent with the types of benefits that are offered to medical staff members by other hospitals in the same region and the compensation is of low value (less than \$25) with respect to each occurrence of the benefit and the compensation arrangement does not violate the Anti-Kickback Law.

\$300 Worth of Non-Monetary Compensation. Another new exception is for non-monetary compensation of up to \$300 per year as long as it does not take into account the volume or value of referrals and is not solicited by the physician or the physician's practice, and does not violate the Anti-kickback law.

Paying Physicians Fair Market Value For Items or Services. The Phase I regulations adopt the broad "fair market value" compensation exception from the proposed rules, except that the final regulations do not require an agreement regarding such compensation to list all other arrangements between the parties. It is also important to note that the final regulations explicitly limit the exception to services rendered by physicians to DHS entities. The requirements for this exception include that there must be a signed, written agreement, which covers only identifiable, specified items or services. The agreement must also specify the timeframe for services, which may be any period of time. The agreement may contain a termination clause, provided the parties entered into one such agreement for the same items and services in the course of a year. There may also be unlimited renewal terms if the agreement is for less than one year, as long as the terms of the compensation arrangement do not vary in the course of a year. The compensation must be set in advance, be consistent with fair market value, not determined in a manner that takes into account the volume or value of any referrals, and be commercially reasonable. The agreement must not violate the Anti-Kickback Law or meet a safe harbor to that law or have been afforded a favorable advisory opinion under the Anti-Kickback Law (interestingly, these statements about safe harbor compliance or receipt of advisory opinions do not appear in the other sections that require Anti-Kickback Law compliance; presumably this is not intended to reflect a substantive distinction). Finally, the services to be performed under the arrangement must not

involve the counseling or promotion of a business arrangement or other activity that violates a state or federal law.

Conclusion

With the promulgation of these Phase I regulations, the health care industry can expect regulatory scrutiny regarding the Stark Law to increase over the coming years. Private "attorneys general" will also be taking note, given the growing popularity of False Claims Act suits based on Stark Law misdeeds. Fortunately, these Phase I regulations clarify a number of points and, accordingly, should be of substantial assistance in structuring legally compliant financial relationships with referring physicians. However, the regulations will also require modification to certain longstanding compensation structures and business relationships, and although the regulations officially take effect a year from now, efforts should begin in order to assure timely compliance.

Has Your Address Changed?

Please let us know if your mailing address needs to be updated. Contact Deborah Chernoff with the correct information either via email: dchernoff@proskauer.com or fax: 212.969.2900. Thank you.

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