

Health Law Alert

A report
for clients
and friends
of the firm May 2004

Stark Law Final Regulations: Phase II

Introduction

The services subject to the federal physician self-referral prohibition (commonly known as the "Stark Law") were greatly expanded in January of 1995 to include, among other things, inpatient and outpatient hospital services and diagnostic imaging. (Social Security Act § 1877; 42 U.S.C. § 1395nn). In January 2001, the Centers for Medicare and Medicaid Services ("CMS") adopted the first of two groups of final regulations (the "Phase I regulations") under the Stark Law (66 Fed. Reg. 856). These regulations dealt with many of the Stark Law provisions, but they did not satisfactorily clarify certain issues and did not address many of the statutory exceptions. The recently issued Phase II Stark regulations (the "Phase II regulations"), effective July 26, 2004, contend with the remaining provisions and resolve many of the issues that the Phase I regulations failed to address (69 Fed. Reg. 16054).

The Stark Law prohibits physicians from referring patients for certain "Designated Health Services" ("DHS") to an entity with which the physician, or an immediate family member of the physician, has a financial relationship. The Phase I and Phase II regulations are an effort to define, with more specificity, the DHS that are included in the above prohibition, what is meant by referrals, and what is meant by a financial relationship. The regulations also clarify the statutory exceptions--those transactions that, according to the statute, are not financial relationships--that will trigger the Stark prohibition. Finally, the regulations lay out their own exceptions to the Stark prohibition. Like the Phase I regulations, the Phase II regulations attempt to balance enforcement of the Stark Law with respect to longstanding provider practices. The Phase II regulations specifically address reporting requirements and sanctions, the compensation exceptions, and all ownership relationship exceptions.

What follows is a discussion of some key points made by the Phase II regulations. The discussion begins with some of the newly clarified definitions, including group practices, inpatient and outpatient hospital services, and nuclear medicine. We then discuss the regulatory treatment of physician compensation under the Stark Law and the statutory and regulatory exceptions to the general prohibition against compensation arrangements. Next we focus on what constitutes a prohibited referral under the statute and regulations. Finally, we focus on the regulatory exceptions, describing how the Phase II regulations clarify and expand on the exceptions put forth in the statute and earlier regulations. This discussion does not, by any means, cover all aspects of the Phase II regulations, and health care providers with potential Stark Law issues should consult with counsel to assure compliance.

Clarifying Certain Stark Law Concepts

Group Practice

The definition of "group practice" under the Stark Law is significant, because it directly impacts the application of several of the more important and substantial statutory exceptions to the overarching self-referral prohibition. A "group practice" is defined as a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association whose primary purpose is to operate a group practice. Operating hospitals are specifically excluded from this definition, although hospitals can form separate entities that operate discreet physician practices or faculty practice plans, and those entities can be group practices under Stark.

While CMS continues with its long-standing interpretation that a group practice cannot be owned by another functioning medical group, the definition of "group practice" is modestly revised, in the Phase II regulations, to permit a group practice to be owned by a shell entity that no longer provided goods and services (*i.e.*, a vehicle for an individual seller or small group practice that had merged into the larger group). Further, the new rules allow a 12-month grace period in certain circum-

stances when a relocating physician is added to the group and the group would otherwise fall out of compliance. Further, the centralized activities of a group practice no longer need to include utilization review services.

Designated Health Services

As explained above, the Stark Law creates a list of services within its purview, identified as DHS. Inpatient and outpatient hospital services are included on this list of DHS. The Phase II regulations make clear that lithotripsy is not included in the definition of inpatient and outpatient hospital services and, therefore, is not on the list of DHS subject to the Stark Law. Nevertheless, contractual relationships between hospitals and physicians or physician practices regarding lithotripsy constitute a "financial relationship" under the Stark Law and must comply with an exception if the physician refers patients to the hospital for services other than lithotripsy that otherwise constitute DHS.

Nuclear Medicine

In response to concerns about nuclear medicine and the "potentially abusive" business arrangements involving physician financial relationships with positron emission tomography ("PET") centers, CMS notes in the Phase II regulations that it is mindful of the potential for abuse and it continues to consider the application of Stark to such procedures. Further, CMS reminds parties that they should be attentive to the fact that the Anti-Kickback Law applies to such relationships. However, CMS does not make changes to the treatment of nuclear medi-

cine procedures under the DHS definitions in the Phase II regulations.

Defining Physician Compensation

The financial relationships that trigger the prohibition on physician referrals are compensation arrangements with an entity that provides DHS, or an ownership or investment interest in such an entity. The compensation arrangement can be direct or indirect and includes remuneration, which, in turn, means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in-kind. The statute creates certain exceptions, however, for compensation arrangements that are not prohibited, and these include a variety of physician compensation arrangements.

Physician Compensation Exception Grid

There are five different physician compensation exceptions and, in an effort to explain these rules, the Preamble to the Phase II regulations sets forth a chart reviewing the varying requirements for physicians in group practices, employment arrangements, personal service arrangements, academic medical centers, and fair market value arrangements. Notably, bonuses based on services "incident-to" personally performed services are available only in the group practice context. Profit-sharing is allowed only in the group practice context, and only the group practice definition (applicable to the in-office ancillary service exception) and bona fide employment exception do not require a

Physician Compensation Exception Grid (69 Fed. Reg. 16067)

Terms of exception	Group practice physicians [1877(h)(4); 411.352]	Bona Fide employment [1877(e)(2); 411.357(c)]	Personal service arrangements [1877(e)(3); 411.357(d)]	Fair market value [411.357(1)]	Academic medical centers [411.355(e)]
Must compensation be "fair market value"?	No	Yes—1877(e)(2)(B)(i) .	Yes—1877(e)(3)(A)(v).	Yes—411.357(1)(3).	Yes—411.355(e)(1)(ii).
Must compensation be "set in advance"?	No	No	Yes—1877(e)(3)(A)(v).	Yes—411.357(1)(3).	Yes—411.355(e)(1)(ii).
Scope of "volume or value" restriction.	DHS referrals—1877(h)(4)(A)(iv).	DHS referrals—1877(e)(2)(B)(ii).	DHS referrals or other business—1877(e)(3)(A)(v).	DHS referrals or other business—411.357(1)(3).	DHS referrals or other business—411.355(e)(1)(ii).
Scope of productivity bonuses allowed.	Personally performed services and "incident to", plus indirect—1877(h)(4)(B)(i).	Personally performed services—1877(e)(2).	Personally performed services—411.351 ("referral") and 411.354(d)(3).	Personally performed services—411.351 ("referral") and 411.354(d)(3).	Personally performed services—411.351 ("referral") and 411.354(d)(3).
Are overall profit shares allowed?	Yes—1877(h)(4)(B)(i)	No	No	No	No.
Written agreement required?	No	No	Yes, minimum 1 year term.	Yes (except for employment), no minimum term.	Yes, written agreement(s) or other document(s).
Terms of exception	Group practice physicians [1877(h)(4); 411.352]	Bona Fide employment [1877(e)(2); 411.357(c)]	Personal service arrangements [1877(e)(3); 411.357(d)]	Fair market value [411.357(1)]	Academic medical centers [411.355(e)]
Physician incentive plan (PIP) exception for services to plan enrollees?	No, but risk-sharing arrangement exception at 411.357(n) may apply.	No, but risk-sharing arrangement exception at 411.357(n) may apply.	Yes, and risk-sharing arrangement exception at 411.357 may also apply.	No, but risk-sharing arrangement exception at 411.357(n) may apply.	No, but risk sharing arrangement exception at 411.357(n) may apply.

written agreement. Compensation is subject to the fair market value requirement in all cases except the group practice definition, and compensation must be set in advance in all cases except the group practice definition and bona fide employment exception. Further, the prohibition on varying payment based on the "volume or value" of referrals is limited to the volume or value of DHS referrals in the group practice and bona fide employment exceptions, but extends more broadly to DHS referrals or other business generated by the physician for the other exceptions. Services personally performed by the referring physician are not considered "other business generated"; however, the corresponding technical components of such services would be considered "other business generated."

Options Are Not Equity

In what appears to be a mistake, CMS maintains its position that options are compensation if they are paid for services, but are not ownership interests under the Stark Law (until they are exercised). This creates a loophole. When options are given as part of an employment relationship, they are clearly compensation. However, once issued, options create an interest of the option holder in the financial performance of the entity. While the option holder cannot receive any part of the profits of the entity during the period before the option is exercised, the ability to exercise the option at a premium in the future if the value of the company is enhanced certainly serves as an incentive for the option holder to make referrals. However, CMS excludes such referrals from the reach of the Stark Law.

Physician Compensation Exception: Percentage Compensation Is Acceptable

In an effort to clarify acceptable physician compensation arrangements, the Phase II regulations expressly authorize percentage compensation arrangements. Such arrangements will be deemed "set in advance" as long as the percentage does not vary based on the volume or value of referrals. The regulations also require that the methodology for determining per unit compensation be fixed in advance and not vary based on referrals; such methodologies are acceptable even if aggregate payments are not fixed, so long as the methodology remains fixed. However, remember that bonuses and percentage compensation cannot be based on DHS merely ordered by the physician, and not personally performed.

One statutory exception permits payments by an employer to a physician if the employment is for identifiable services and the payment is for fair market value without reference to any referrals by the physician to the employer. In the Phase II regulations, CMS adopts a new regulatory safe harbor for calculating the fair market value of physicians' hourly services. The safe harbor provides two methodologies for calculating acceptable hourly rates. The first methodology permits hourly payments "less than or equal to the average hourly rate for emergency room physician services in the relevant physician market." The second methodology requires averaging the 50th percentile

salary for the physician's specialty as established by four recognized physician compensation surveys and dividing this average by 2,000 hours to obtain an acceptable hourly rate.

Mandated Referrals

The Phase I regulations explicitly permitted limited compensation arrangements that included required referrals to a particular provider. Now, in Phase II, CMS clarifies that referrals may be required only if they are solely related to the services the physician is performing pursuant to the arrangement and the required referrals are reasonably necessary to effectuate the legitimate purposes of the compensation relationship.

Indirect Compensation Relationships

While the Phase I regulations devoted considerable attention to "indirect" compensation relationships between referring physicians and an entity that provides DHS, the bright-line rules crafted in the earlier regulations raised serious questions. The Phase II regulations clarify the "indirect compensation relationship" definition and exception to make clear that variable payments tied to any business generated between the parties would be included in the definition of "financial relationship" and, thus, trigger the prohibition on physician referrals. However, the indirect compensation arrangement exception would protect per unit or percentage payments to the physician with the indirect compensation relationship.

Physician Relocation Payments

The physician recruitment exception permits certain remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital. This exception has been modified so that all physicians ending formal training programs are deemed to be relocating physicians. Recruitment payments made through existing medical groups are permitted under very limited circumstances that assure that the benefit goes directly to the recruited physician. This exception applies only to recruitment by hospitals and federally qualified health centers.

Physician Retention Payments in HPSA

The Phase II regulations add a new exception for retention payments for physicians who practice in a health professional shortage area where the physician has a firm, written recruitment offer from an unrelated hospital that would require the physician to move his or her practice at least 25 miles and outside of the geographic area served by the hospital. The excepted payment must be limited to the lower of (i) the difference between the offer and current compensation or (ii) the reasonable costs of recruiting a new physician to join the staff. The hospital may enter into only one retention agreement with the physician every five years, and the payments under such agreements cannot be based on the volume or value of the business generated by the physician. The retention exception does not allow payments to or through groups.

Isolated Transactions

One statutory exception to the compensation arrangement prohibition permits one-time, isolated transactions, such as the sale of a medical practice, provided the amount paid in the transaction represents the fair market value and there is no reference to physician referrals. This one-time, isolated transaction exception is clarified in the Phase II regulations to permit post-closing adjustments if they are commercially reasonable, not dependent on referrals or other business generated by the referring physician, and made within six months of the date of the purchase or sale transaction. Installment payments are permitted if they are set before the first payment is made, do not take into account the value or volume of business generated by the referring physician, and the outstanding balance is guaranteed by a third party, secured by a negotiable promissory note or subject to a similar mechanism that protects the payee in the event of financial problems of the payor entity.

Unrelated Remuneration

CMS emphasizes in Phase II that the statutory exception for remuneration unrelated to the provision of the DHS is intended to be very limited. Remuneration must be "wholly unrelated" to the provision of DHS. Any item, service or cost that would have been payable, in whole or in part, by Medicare or Medicaid will be deemed to be related to DHS. In addition, even if not includible within the cost report, if remuneration is otherwise related to DHS, even if indirectly, such as a hospital lease of a nearby office space to a physician who could refer to the hospital, the remuneration would not benefit from this exception. To the extent that the comments in the preamble to the January 1998 proposed Stark regulations suggested that general administrative and regulatory review services were not related to DHS, they are now withdrawn.

Sub-Contracting of Personal Services

Certain personal service arrangements in which a physician receives remuneration for certain pre-determined services are also excepted from the general prohibition. Under the Phase II regulations, however, the personal services exception is not available to a physician or group that contracts with a DHS provider for personal services and then subcontracts with an independent contractor to provide such services.

Non-Competes May Be Acceptable

CMS notes in the regulations that non-compete provisions in employment agreements are acceptable so long as the payment for the non-compete covenant is at fair market value. The inclusion of such provisions in space and equipment leases, however, might raise issues regarding compliance with those exceptions.

Mixed Equipment and Personal Services Contracts

CMS also states that it will allow equipment and personal services to be provided by the same entity pursuant to the same agreement, although for purposes of determining fair market value, CMS will separate services and equipment.

Cross-Referencing of Contracts

In regard to the prior requirement that all agreements between the parties be cross-referenced, CMS now permits cross-referencing to a master list of relationships between the entity and the physician that is maintained and updated centrally.

Physician Purchased Diagnostic Services

CMS makes clear that billing for purchased diagnostic services is not prohibited by Stark. (In this situation the technical diagnostic service purchased by the physician or group are not "marked up" in billing Medicare.)

Exceptions to the General Prohibition on Referrals

Stark Law defines a "referral" as any request for DHS for which payment may be made under Medicare Part B or a request for a consultation with another doctor who may order DHS. Referrals of DHS to an entity with which the referring physician has a financial relationship are generally prohibited, although Stark does provide certain exceptions to this general rule.

The In-Office Ancillary Services Exception and the Same Building Requirement

One example of an exception to the general prohibition on referrals is for in-office ancillary services: Stark does not forbid referrals for most services that are referred by a solo practitioner or group practice member within his or her own practice, so long as certain requirements are met. This is the exception upon which group practices most often rely. In the Phase II regulations, CMS seeks to clarify the in-office ancillary services exception, particularly for group practices. The Phase II regulations provide, for example, that the exception extends, in the case of a group, to a central building used for some or all of a group practice's DHS, so long as the group has full-time, exclusive ownership or occupancy of the centralized space.

The in-office ancillary services exception requires that DHS must be furnished to patients in the same building where the referring physicians provide their regular medical services, or, in the case of a group practice, in a central building, provided certain conditions are satisfied. The Phase II regulations establish three tests, only one of which must be satisfied, for physicians and groups to meet the "same building requirement." The first test is satisfied if the building is one in which the referring physician or group practice has an office that is normally open to patients for medical services at least 35 hours per week, the referring physician or group practice member provides physician services in that office at least 30 hours per week, and "some" of these services are not related to the furnishing of DHS. The second test is satisfied if the building is one where the referring physician or group practice owns or rents an office that is normally open to patients for at least eight hours per week, the referring physician or group practice regularly practices medicine and furnishes services to patients at that site at least six hours per week including "some" services unrelated to DHS, and the patient receiving the DHS usually sees the refer-

ring physician or other member of the referring physician's group practice at that site. The third test is satisfied if the building is one where the referring physician or group practice owns or rents an office that is normally open to patients for at least eight hours per week, the referring physician or group practice regularly practices medicine and furnishes services to patients at that site at least six hours per week including "some" services unrelated to DHS, and where the referring physician is present and orders the DHS in connection with a patient's visit during the time the office is open in the building, or the referring physician or a member of the physician's group practice is present while the DHS is furnished during the time the office is open in the building. CMS has refused to define more particularly "some," saying only that it should be interpreted in its common sense meaning.

Physician Self-Referral

CMS, in the Phase II regulations, again emphasizes that a referral for a physician service, even a referral for a Stark-covered DHS, is not a prohibited referral when personally performed or provided by the referring physician.

Intra-family Referrals: Rural Areas

Another exception to the general prohibition on referrals is for intra-family referrals in rural areas, where necessary due to the absence of other providers.

Regulatory Exceptions

Academic Medical Centers

The Phase I regulations contained an exception for academic medical centers ("AMCs") that permitted certain physician-hospital compensation or ownership/investment relationships if the physician is a bona fide employee of the AMC. The AMC exception, which was confusing and essentially unworkable as originally drafted, is modified and clarified in a very helpful manner in the Phase II regulations. The definition of AMC is broadened to include accredited medical schools, accredited academic hospitals (*i.e.*, a hospital with four or more approved medical education programs and in which a majority of the physicians on the medical staff are faculty members), affiliated hospitals (*i.e.*, a majority of medical staff are faculty members and a majority of admissions are by faculty members) and affiliated faculty practice plans. The affiliated faculty practice plan no longer needs to be organized in any particular manner, and more than one plan may exist for the AMC. The faculty practice plan may be affiliated with the medical school or the accredited academic hospital.

The AMC exception requires that the referring physician be a bona fide employee of a component of the AMC. The referring physician must be licensed and have a bona fide faculty appointment at the medical school or in one or more educational programs at the accredited academic hospital, and must provide either substantial academic services or substantial clinical teaching services for which the referring physician is compensated as part of the employment relationship with the AMC.

The new exception provides a "safe harbor" in regard to the definition of substantial academic services or substantial clinical teaching services, providing that any referring physician shall meet such definition if he or she spends at least 20% of his or her professional time or eight hours per week providing such services. Failure to meet the safe harbor will not preclude other evidence of such services, which are not more particularly defined; CMS notes that "[a]cademic medical centers should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services" and that "the substantial services test can be met through either academic services (which would include, without limitation, both classroom and academic research services) or clinical teaching services, or a combination of both." The total compensation paid to the referring physician can be paid by different components of the AMC, but it must be set in advance and, in the aggregate, must not exceed fair market value without taking into account the volume or value of referrals or business generated by the referring physician. Further, all transfers of money between components of the AMC must directly or indirectly support the missions of teaching, indigent care, research, or community service. The relationship of the components of the AMC must be set forth in a written agreement adopted by the governing body of each component. Finally, any payment to the referring physician for research must be used for bona fide research or teaching and be consistent with the grant and the financial relationship with the referring physician, and must not violate the Anti-Kickback Law or other federal law governing billing or claim submission.

Medical Staff Incidental Benefits and Non-Monetary Compensation

The Phase I regulations contained exceptions for "Medical Staff Incidental Benefits" and "Non-Monetary Compensation" which the Phase II regulations have altered in certain respects. Entities can provide physicians with non-monetary items or services, if they are not cash or cash equivalents and if the compensation does not exceed an aggregate of \$300 per year. Hospitals are permitted to provide incidental benefits on the hospital campus, so long as the value of each "benefit" is less than \$25 and they are not in the form of cash or cash equivalents. The Phase I regulations required that these incidental benefits be commensurate with the types of benefits offered to staff members in other local or regional hospitals. The Phase II regulations eliminate this requirement; incidental medical staff benefits no longer have to be commensurate with those offered by other hospitals. The Phase II regulations also alter the "hospital campus" requirement to permit the use of internet services, pagers, and two-way radios away from the hospital. Further the Phase II regulations specify that both the incidental medical staff benefits and the \$300 per year non-monetary compensation exception - the "de minimis compensation exception" - are indexed for inflation.

Charitable Donations; Professional Courtesy; Community Wide Information Systems

CMS creates, in the Phase II regulations, certain new exceptions to the Stark Law. A new exception is created for charitable donations from physicians to an entity that provides DHS in circumstances where the donation is not solicited or made in any manner that reflects the volume or value of referrals generated from one party to the other. CMS notes that "[b]road-based solicitations not targeted specifically at physicians, such as sales of charity ball tickets or general fund-raising campaigns, will qualify under this exception." A new and very limited exception is added for professional courtesy discounts. A new exception for community-wide information systems is adopted, although it is highly restrictive. For example, the community-wide health information system must be available to all providers, practitioners and residents of the community who desire to participate, the agreement cannot violate the Anti-Kickback Law, and items or services provided to the physician must be principally used by the physician as part of the community-wide health information system (*i.e.*, provision of a computer would not generally meet this requirement).

Grace Periods

CMS provides a general grace period for certain arrangements that have fully satisfied another exception for at least 180 consecutive days, but have temporarily fallen out of compliance.

Reporting Requirements

The regulations establish a basic reporting requirement. All entities furnishing services for which payment may be made under Medicare must submit information to CMS or the Office of Inspector General at the agency's request concerning their reportable financial relationships. The entities that are subject to this requirement must submit the required information within the time period specified by the request. However, the entity must be given at least 30 days from the date of the request to provide the information. The information that must be reported includes the name and physician identification number of each physician who has a reportable financial relationship with the entity, the name and physician identification number of each physician who has an immediate family member who has a reportable relationship with the entity, the covered services furnished by the entity, and the nature of the financial relationship with each physician.

Conclusion

We touch on only a few of the newly clarified issues in the Phase II regulations -- the full regulations are certainly worthy of attention. As we forewarned in our Client Alert on the Phase I regulations, the passage of these regulations will likely increase the regulatory scrutiny of the health care industry over the coming years. We note, however, that the Stark Law will most likely be enforced through *qui tam* relators relying on the

False Claims Act to seek redress (and substantial bounties). The Phase II regulations, like the Phase I regulations, provide significant guidance to health care facilities and physicians who are structuring financial relationships and creating referral policies. The July 26, 2004 compliance deadline for the Phase II regulations is fast approaching and efforts should begin immediately to ensure compliance by that time.

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