

STARK II PHASE II is Here- Have You Analyzed Your Healthcare Clients' Financial Relationships?

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When structuring many common business relationships involving healthcare providers, attorneys must be aware of the myriad federal and state laws that may be implicated as a result of the arrangement. The healthcare industry is heavily regulated with laws governing practices that may be entirely legal in other industries, but are limited or prohibited in the healthcare arena. This article will present a brief summary of the federal anti-kickback law, which may be implicated in many healthcare transactions. The focus of this article, however, is on the recently published Stark II Phase II Final Regulations, which apply to many common healthcare arrangements.

The Federal Anti-Kickback Statute

The anti-kickback statute provides criminal and administrative penalties for persons and entities on either side of a transaction that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business for which payment may be made by a federal healthcare program. As written, the statute is very broad, covering a vast array of common healthcare arrangements. The courts have held that if one purpose of the payment of remuneration was to induce referrals of services, the statute has been violated. When the statute has been violated, the government may proceed criminally or administratively. A criminal violation of the statute is a felony punishable by up to five years in prison, a fine of up to \$25,000, and mandatory exclusion from participation in all federal healthcare programs. If the government opts to proceed civilly, it may impose a civil monetary penalty of \$50,000 per violation and an assessment of not more than three times the total amount of remuneration involved. Additionally, it may also exclude either party from participating in all federal healthcare programs.¹

In recognition that there are many legitimate healthcare arrangements, Congress included certain statutory exceptions that describe activities that will not implicate the kickback prohibition including: 1) discounts, 2) payments to bona fide employees, 3) certain amounts paid by providers to a group purchasing organization, 4) certain waivers of coinsurance and deductibles, and 5) certain risk-sharing arrangements. In addition to the statutory exceptions, the Secretary of the Department of Health and Human Services (“DHHS”) specified other transactions that will be afforded protection from the anti-kickback statute. These regulations are referred to as the “Safe Harbor Regulations.” An arrangement that fits into one or more of the statutory exceptions or safe harbors is immune from prosecution. Notably, however, such protection

is only afforded to those arrangements that fit squarely within all of the conditions of the exception or safe harbor. It should also be noted that just because an arrangement does not fit squarely within a safe harbor or exception does not mean that the arrangement is per se illegal. Rather, the relationship must then be carefully scrutinized in its entirety based upon the totality of the facts and circumstances. There are currently 24 safe harbors. Of particular importance to attorneys who are structuring business arrangements for physicians or other healthcare providers are the safe harbors for: 1) space and equipment leases, 2) investment interests, 3) personal services and managements contracts, 4) sale of medical practice, 5) physician recruitment, 6) group practices, and 7) coinsurance and deductibles.²

Stark II

On March 26, 2004, the Centers for Medicare and Medicaid (“CMS”) issued the long-awaited Phase II Final Stark Regulations. In 1998, CMS first issued the proposed Stark II regulations. CMS split the final rulemaking process into two phases. Phase I was issued in 2001, leaving Phase II until now. In Phase II, CMS addresses the comments received from Phase I, making some revisions, as well as providing final regulations on the provisions of the Stark II law that had not been addressed.³

While Phase II provides greater flexibility, attorneys advising physicians and healthcare providers must keep in mind that they cannot ignore Stark, as nearly every financial relationship between physicians and entities that furnish designated health services (“DHS”) implicate Stark. Physicians and entities furnishing DHS must be in compliance with the new regulations by July 26, 2004. Violations of the law have substantial consequences for all parties involved, regardless of the intent of the parties. Sanctions include denial of payment for DHS claims, civil monetary penalties (\$15,000 for each claim submitted plus two times the reimbursement claimed), and exclusion from Medicare and Medicaid. In addition, parties who enter into circumvention schemes are subject to a civil monetary penalty of up to \$100,000 per scheme.

Although the majority of the modifications in Phase II of the rulemaking process reflect a good-faith effort by CMS to implement the Stark law in a more practical manner, healthcare providers must be prepared to document their compliance with Stark. Attorneys advising healthcare clients must be aware of the Phase II reporting requirements and general documentation requirements, which are incorporated throughout the various exceptions. Documentation supporting compliance is particularly important in today’s healthcare environment, which has had an increase in Federal False Claims litigation and investigations stemming from Qui Tam whistleblowers utilizing technical violations of Stark as a predicate for False Claims Act violations.

What Do the Regulations Mean for Physicians and Health Care Providers?

Stark prohibits physicians from referring Medicare/Medicaid beneficiaries to an entity in which they (or an immediate family member) have a financial relationship for DHS. DHS include: clinical lab; physical therapy; occupational therapy; radiology (including MRIs, CAT scans, and ultrasounds); radiation therapy and supplies; 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 hospitalization services.

Many common financial relationships can trigger the need for a Stark analysis. Examples of common healthcare relationships that can trigger Stark include, without limitation: 1) physician independent contractor agreements, 2) lease agreements for equipment or space, 3) physician employment contracts with group practices and hospitals, 4) medical director agreements, 5) hospital-physician recruitment agreements, 6) managed care risk-sharing compensation, and 7) arrangements between physicians and other DHS providers (e.g., home health agencies and DME companies).

Notably, Stark even applies to referrals of DHS within a group practice. For example, if a group practice provides services such as physical therapy, clinical lab, x-rays, and/or ultrasounds within the practice, Stark will be implicated. Once the prohibition is triggered, the relationship must then fall within a Stark exception.

Highlights of the Phase II Regulations

The remainder of this article will summarize some of the highlights of Phase II, which are of particular importance to attorneys structuring or advising physicians or healthcare clients with regard to their business transactions and financial relationships.

Physician Compensation

Phase II provides clarification and modifications as to how physicians can be compensated under the various exceptions for physician compensation. These exceptions vary based upon whether the physicians are physicians in a group practice, employees or independent contractors. Phase I of the rulemaking also created new regulatory exceptions for fair market value compensation paid to employees or independent contractors and compensation for academic medical center physicians. In response to the Phase I regulations, CMS received many comments regarding physician compensation with a common theme that there should only be one set of conditions applicable to physician compensation. In response to these comments, the Phase II preamble makes clear that the statute itself favors group practices by allowing group practices to

divide revenues among their physicians in ways that are very different from the ways in which other DHS entities are allowed to share revenues with employed and independent contractor physicians.⁴ Specifically, with regard to “incident to” services, the statute allows group practices to compensate physicians regardless of employment status (e.g., owner, employee, or independent contractor). Moreover, the statute allows group practices to compensate indirectly for other DHS referrals.⁵

In an attempt to equalize the other aspects of physician compensation with respect to physician compensation outside of the group practice context, Phase II sets forth several modifications and clarifications in the regulations and preamble commentary. Notwithstanding these attempts, caution should still be taken when analyzing physician compensation as the specific terms and conditions of each exception continue to differ in some respects. As a result of Phase II, under the employment, personal services, fair market value, and academic medical centers exceptions, physician compensation can be based on the following: 1) a percentage of revenues or collections for personally performed services, 2) productivity bonuses on any personally performed services, and 3) risk-sharing payments made pursuant to participation in a physician incentive plan related to health plan enrollees.

Percentage Compensation

The two main exceptions utilized by independent contractors – personal service arrangement and fair market value – require that the compensation that the physician receives be “set in advance.”⁶ Phase I interpreted “set in advance” to prohibit most percentage compensation arrangements, thereby restricting compensation structures for physicians practicing as independent contractors relying upon these compensation exceptions. Phase II modifies this interpretation to permit some percentage compensation arrangements. As a result, like their group practice and employee counterparts, independent contractors can now receive limited forms of percentage compensation.⁷

Productivity Bonuses

In response to Phase I, commenters also expressed concern regarding the ability of physicians to receive productivity bonuses outside of the group practice/in-office ancillary context. Phase II modifies the regulations to clarify that all physicians – whether employees, independent contractors, or academic medical center physicians – can be paid productivity bonuses based on work they personally perform. Physicians, however, must keep in mind that: any technical component of a service corresponding to the personally performed service is not considered work they personally perform.⁸

The In-Office Ancillary Services Exception

The in-office ancillary services exception has been arguably the single most important exception in the Stark law. This exception is designed to protect the in-office provision of certain DHS that are genuinely ancillary to the medical services provided by the practice. The in-office ancillary exception exempts services personally provided by the referring physician; a physician who is a member of the same group practice as the referring physician; an individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all of the Medicare payment and coverage rules for the services. In addition, the exception contains a location and a billing requirement. The in-office ancillary services exception covers nearly all DHS except durable medical equipment (other than a few carve-outs for certain types of infusion pumps, blood glucose monitors, and certain other devices that provide assistance to patients leaving the physician's office), and parenteral and enteral nutrients, equipment and supplies.⁹

Under the in-office ancillary services exception, 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 centralized building.¹⁰ These location rules were designed to give physicians and group practices an important opportunity to provide ~~bona-~~
~~fide~~bona fide in-office ancillary DHS to their patients, while at the same time preventing group practices from using the exception to operate self-referred DHS enterprises. A group practice can satisfy the location requirement by either meeting the "same building" test or the "centralized building" test. Phase II of the regulations develops three new alternative "same building" tests to replace the Phase I three-part test in its entirety. Only one of the three tests must be satisfied to meet the "same building" requirement and all three tests are available to both solo practitioners and group practice physicians. Under all three tests, referring physicians or group practice members must have offices in the building that are normally open to their patients a requisite number of hours per week. All three tests also require that the physician regularly practice medicine and furnish physician services for a minimum number of hours per week in that office.¹¹

Group Practice Definition

The group practice definition is not an exception to the self-referral prohibition in and of itself, but it has significant meaning to any group of physicians who want to take advantage of the in-office ancillary services and physician services exceptions. Phase II of the rulemaking clarifies certain aspects of the definition and created new aspects including grace periods for non-compliance, deletion of the utilization review requirements, and allowance for bonuses or profit distributions based directly on "incident to services."¹²

Group practices that choose to take advantage of the special treatment that the Stark law affords them must be prepared to demonstrate compliance with relevant statutory and regulatory standards. In this regard, if requested by the Secretary, group practices are required to provide documentation of the total time each member spends on patient care services and to maintain documentation supporting compliance with the “substantially all” test. The “substantially all” test is intended to guarantee that the group practice members are providing a substantial amount of their services through the group. Groups can document compliance by any reasonable means, including time cards, appointment schedules, personal diaries, or other reasonable means that are fixed in advance of the performance of the services being measured, uniformly applied over time, and verifiable. Groups are also required to document, in writing, a new member’s employment with, or ownership or investment in, the group practice before the new relationship commences.¹³

Rental of Space or Equipment

Phase II of the regulations makes several minor changes to the 1998 proposed regulations regarding rental of office space and equipment. In order for an office space or equipment lease to meet the exceptions, the following requirements must be met: 1) the lease is in writing, signed by the parties, and specifies the space or equipment covered by the lease; 2) the term of the agreement is at least one year; 3) the space or equipment rented or leased does not exceed what is reasonable and necessary for the legitimate business purposes of the lease, and is used exclusively by the lessee when being used by the lessee (except that prorated payments for common areas are allowed); 4) the rental charges over the term of the lease are set in advance and are consistent with fair market value; 5) the rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and 6) the agreement would be commercially reasonable even if no referrals were made between the parties.¹⁴ For purposes of these exceptions, “fair market value” means the value of the rental property for general commercial purposes (not taking into account the property’s intended use). In addition, for rentals or leases where the lessor is a potential source of patient referrals to the lessee, fair market value means general commercial value not taking into account the intended use or the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor.¹⁵

Phase II makes several minor changes to the exceptions to allow “without cause” provisions, holdover leases for a period of up to six months, and subleases, provided certain conditions are met. ~~Phase-~~ CMS also changed its original interpretation regarding lease types to reflect that the lease exceptions apply to both operating and capital leases.

Fair Market Value Safe Harbor

In a continued effort to provide “bright line” rules, Phase II creates a safe harbor provision for DHS entities making payments to a physician for his/her personal services. Notably, this safe harbor provision provides that an hourly payment for a physician’s personal services (not services performed by employees, contractors, or others) shall be considered fair market value if the hourly payment is established using either of the following two methods: 1) the hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided that there are at least three hospitals providing emergency room services in the market; or 2) the hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or if a specialty is not identified, for general practice) in at least four surveys (as identified in the regulations), divided by 2,000 hours.

Although compliance with these safe harbor methodologies is entirely voluntary, DHS entities that choose to use either of these bright line methods will be assured that their compensation will be deemed fair market value.¹⁶

Academic Medical Centers

Phase II makes many revisions and clarifications to the academic medical center (“AMC”) exception in order to make it easier to qualify. Modifications to the exception include, without limitation: 1) allowing hospitals or health systems to substitute for an accredited medical school provided certain conditions are met, 2) eliminating the requirement that the faculty practice plan be organized in any particular manner, (3) clarifying that an AMC may have more than one affiliated faculty practice plan, and (4) covering research money used for teaching, a core AMC function.¹⁷

Physician Recruitment

Phase II of the rulemaking process significantly modifies the physician recruitment exception. Some of the more notable modifications made to this exception include: 1) looking to the relocation of the recruited physician’s medical practice, rather than his/her residence; 2) expanding the exception to apply to federally qualified healthcare centers; 3) allowing hospital payments to be made directly to

medical groups in connection with the recruitment of new physicians; and 4) carving out residents and physicians in the practice one year or less from the relocation requirement.¹⁸

Professional Courtesy

In recognition of the long-standing tradition and widespread practice of extending professional courtesy to physicians and their families, Phase II creates an exception allowing entities to extend “professional courtesy” to a physician, members of the physician’s immediate family, or members of the physician’s office staff pursuant to several conditions. In addition to other conditions, if the professional courtesy policy involves the reduction in coinsurance, the entity must notify the insurer in writing of the reduction. Moreover, the professional courtesy cannot be offered to a physician (or immediate family member) who is a federal healthcare program beneficiary, unless there has been a good-faith showing of financial need.¹⁹

Temporary Noncompliance

Phase II creates an exception to protect against inadvertent noncompliance with Stark. This exception was prompted in response to several commenters who requested some type of “grace period” for parties unable to comply with an exception for temporary periods of time. In order to qualify for this exception, parties must meet the following conditions: 1) the financial relationship between the entity and the referring physician fully complied with an applicable exception (under 42 CFR §§ 411.355, 411.356, or 411.357) for at least 180 days prior to the date the relationship became noncompliant; 2) the relationship fell out of compliance for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; 3) the relationship does not violate the anti-kickback statute, and the claim or bill otherwise complies with all applicable rules and regulations; 4) the exception applies only to DHS furnished during the period of time it takes the entity to rectify noncompliance, which must not exceed 90 consecutive calendar days; and 5) the exception may only be used once every three years with respect to the same referring physician. It should be noted that that this exception does not apply for relationships under the ‘non-monetary compensation up to \$300’ exception or the medical staff incidental benefit exception.²⁰

Parties taking advantage of this exception should take caution to properly document the reasons for noncompliance and the steps taken to rectify the situation. In order to avoid penalties for violations of Stark, CMS notes that by the end of the 90-day period, parties must either comply with an exception or have terminated their otherwise prohibited relationship.²¹

Reporting Requirements

The Stark law contains a reporting provision requiring all entities to submit certain information to the Secretary of DHHS. Up until Phase II, these reporting requirements were not addressed by the final regulations. Phase II finally addresses these requirements, making several modifications. The final rule requires that, if requested by CMS or the Office of the Inspector General (“OIG”), all entities (except those furnishing 20 or fewer Part A or Part B services in a calendar year or those furnishing services outside of the United States) submit certain information. The information that can be requested by CMS or OIG includes: 1) the name and unique identification number (“UPIN”) of each physician who has a “reportable financial relationship” with the entity, 2) the name and UPIN of each physician who has an immediate family member who has a “reportable financial relationship” with the entity, and 3) the covered services furnished by the entity.²²

For purposes of the reporting requirements, a “reportable financial relationship” means any ownership or investment interest (as defined in 42 CFR § 411.354(b)) or any compensation arrangement (as defined in 42 CFR § 411.354(c)), except for ownership or investment interests that satisfy the exceptions set forth in 42 CFR §§ 411.356(a) or (b) regarding publicly traded securities and mutual funds.²³ Although interests in publicly traded securities and mutual funds are excluded from the reporting requirements, this exclusion is strictly limited to shareholder information. As a result, contractual arrangements concerning these interests are still reportable. 69 Fed. Reg. at 17933.*

General Documentation

There are numerous documentation requirements incorporated throughout the various Stark exceptions. In this regard, physicians and providers should be prepared to document their compliance with Stark. A few examples include with the following: 1) group practices should document compliance with the “substantially all” test; a new member’s employment with, or ownership in, a group practice; and the total time each member spends on patient care services; 2) group practices should document the method used to calculate profit shares or productivity bonuses and the resulting amounts of compensation; 3) academic medical centers should document the relationship between the components of the AMC, and compliance with “substantial academic” or “substantial teaching” services for purposes of the referring physician’s services; 4) entities relying upon the space and equipment rental agreements, personal services arrangements, physician recruitment, fair market value compensation, and indirect compensation exceptions must maintain a signed written agreement of the arrangement; 5) entities and physicians relying upon the fair market value safe harbors for payment for a physician’s personal services should document compliance with the safe harbor; 6) entities that take advantage of the professional courtesy exception should have the policy set out in writing and be prepared to provide documentation that its insurers were notified with respect to any reductions in coinsurance offered as part of the policy; 7)

parties entering into personal service arrangements must be documenting all separate arrangements between the parties either by incorporation by reference or by maintaining a master lists of contracts; and 8) parties that fall out of temporary compliance with an exception should document the reasons for the temporary non-compliance and the actions taken to rectify the situation.

Conclusion

This article is intended as only a brief summary of Stark II Phase II. It does not cover every aspect of the regulations. Attorneys advising their healthcare clients regarding potential relationships that may implicate the self-referral ban should carefully scrutinize the statute and implementing regulations. Attorneys counseling healthcare providers must also remain mindful of the federal anti-kickback statute and state laws regarding self-referrals. ~~42 U.S.C. Section 1320a-7b. Individuals involved in financial relationships that may implicate Stark's ban may also run afoul of the anti-kickback statute.~~ Although many of the Stark exceptions appear similar to the anti-kickback safe harbors, they are not identical and require separate examination. Attorneys should also stay alert for Phase III of the regulations which will address comments received on the March 26, 2004, Phase II Interim Final Rule.

* It should be noted that FR Doc. 04-6668 of March 26, 2004 (69 Fed. Reg. 16054) was published with a technical error. CMS inadvertently omitted two sections from the preamble document, Section IX Reporting Requirements and Section X Sanctions. These two sections were published on April 6, 2004 in a Corrections of Errors notice (69 Fed. Reg. 17933).

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Footnotes

- 1 42 USC § 1320a-7b(b).
- 2 42 CFR § 1001.952.
- 3 69 Fed. Reg. 16054 (2004).
- 4 69 Fed. Reg. at 16066.
- 5 42 USC § 1877(h)(4)(B)(i).
- 6 42 CFR §§ 411.357(d) and (l).
- 7 42 CFR § 411.354(d)(1).
- 8 69 Fed. Reg. at 16067-16068.
- 9 42 CFR § 411.355(b).
- 10 42 CFR §§ 411.355(b)(2)(i) and (ii).
- 11 42 CFR § 411.355(b)(2).
- 12 42 CFR § 411.352.
- 13 42 CFR § 411.352(d)(2).
- 14 42 CFR §§ 411.357(a) and (b).
- 15 42 CFR § 411.351.
- 16 42 CFR § 411.351.
- 17 42 CFR § 411.355(c).
- 18 42 CFR § 411.357(e).
- 19 42 CFR § 411.357(s).
- 20 42 CFR § 411.353(f).
- 21 69 Fed. Reg. at 16057.
- 22 42 CFR § 411.361.
- 23 42 CFR § 411.361(d).

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