



THE STARK II, PHASE II REGULATIONS: A LEGAL OVERVIEW

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A LEGAL OVERVIEW OF THE STARK II, PHASE II REGULATIONS

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I. Introduction

In one of the most significant federal regulatory developments in the past five years, on March 26, 2004, the Centers for Medicare & Medicaid Services (“CMS”) published the long-awaited “Phase II Regulations”² interpreting and implementing the federal physician self-referral law (“Stark Law”).³ Like the “Phase I Regulations,” which were published in 2001, the Phase II Regulations depart in a number of significant respects from the 1998 “Proposed Rule” upon which both sets of Regulations are based. Also like the Phase I Regulations, the Phase II Regulations “endeavor” — with some success — “to reduce the burden and prescriptive nature” of the Stark Law.⁴

This paper provides highlights, along with some analysis, of the Phase II Regulations. A few caveats are in order, however. The Phase II Regulations, together with their preamble, occupy almost 100 pages of Federal Register text. Moreover, these Regulations are just the latest piece of a complex statutory and regulatory puzzle that has evolved in fits and starts — and not without controversy — over the past 15 years. Under these circumstances, and in a paper of this length, it is not possible to address each and every provision of the Phase II Regulations.

What is clear, however, is that the Phase II Regulations will have a significant impact on the health care industry in general and on physician-provider arrangements specifically for years to come. Simply put, there are thousands upon thousands of formal and informal arrangements

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² 69 Fed. Reg. 16054 (March 26, 2004).

³ 42 U.S.C. § 1395nn.

⁴ 69 Fed. Reg. at 16055.

involving physicians, hospitals, and other providers that involve something of value — cash, goods, services, etc. — flowing between and among the parties. Each and every one of these arrangements, regardless of how nominal or common-place the compensation at issue, potentially implicates the Stark Law. Moreover, the sanctions associated with a Stark Law violation can be astronomical, and completely out of proportion to the gravity of the offense.

For all of these reasons then, a full and clear understanding of the Phase II Regulations is critical to physicians, providers, and the in-house and outside counsel who advise them. Again, this paper is intended to be a first, small step in this process. As discussed more fully below, a sample of the more significant developments reflected in the Phase II Regulations are as follows:

- The Regulations create seven new exceptions, covering (1) charitable donations by physicians, (2) hospital referral services, (3) obstetrical malpractice insurance, (4) professional courtesy, (5) payments to retain physicians in medically underserved areas, (6) the provision of community-wide health information services, and (7) intra-family referrals in rural areas.
- The Regulations create a new (if quite limited) safe harbor for certain arrangements that have “unavoidably and temporarily fallen out of compliance” with a Stark Law exception.
- The Regulations simplify, clarify, and/or expand a number of exceptions, including those covering leases and personal services arrangements.
- The Regulations substantially modify the exception for physician relocation and recruitment arrangements.
- The Regulations continue the process of defining certain common Stark Law terms — such as “volume or value,” “set in advance” and “fair market value” — in a manner that is more consistent with industry practices. For example, the Phase II Regulations modify the “set in advance” definition to permit percentage compensation arrangements.
- The Regulations continue the now five-year old — and largely unsuccessful — process of developing a logical, internally consistent, and easily applicable “indirect compensation arrangement” test and exception.

II. Background

The Stark Law prohibits a “physician” from “referring” patients “to” an “entity” for the “furnishing” of “designated health services” (“DHS”) covered by Medicare if the physician (or one

of his or her “immediate family members”) has a “financial relationship” with the entity unless the relationship fits within an exception.⁵ The Stark Law also prohibits an entity that has provided DHS to an improperly-referred patient from (1) submitting a claim for reimbursement for such DHS or (2) otherwise billing any person or entity for such DHS.⁶

The original Stark Law (“Stark I”) was enacted in 1989 and Stark I regulations were proposed in 1992 and issued in 1995 (“Stark I Regulations”). Stark I was significantly expanded in 1993 (“Stark II”). The Stark II Proposed Regulations were issued in 1998 and finalized in 2001 (Phase I Regulations) and 2004 (Phase II Regulations).

The Phase I Regulations addressed those sections of the Stark II Proposed Regulations concerning (1) the general prohibition on referrals, (2) certain definitions used throughout the Stark Law, and (3) the exceptions that protect referrals regardless of the form of the underlying financial relationship (“All Purpose Exceptions”). The Phase I Regulations also created six new exceptions covering financial relationships that take the form of a compensation arrangement (“Compensation Arrangement Exceptions”).

The Phase II Regulations address (1) exceptions covering financial relationships that take the form of an ownership interest (“Ownership Interest Exceptions”), (2) the 15 Compensation Arrangement Exceptions in place following issuance of the Phase I Regulations, (3) the Stark Law’s reporting requirements, and (4) the Stark Law’s sanction provisions. The Phase II Regulations also respond to comments submitted on the Phase I Regulations, modifying many of the positions, and rules, previously adopted by CMS. Finally, the Phase II Regulations create six new Compensation Arrangement Exceptions and create (and delete) one All Purpose Exception.⁷

This Article addresses the Phase I and Phase II Regulations wholistically, highlighting both the new provisions set forth in the Phase II Regulations, as well as some of the more significant modifications, additions and deletions made to the Phase I Regulations. The Article is divided into sections covering:

- Definitions (Section III).

⁵ 42 U.S.C. § 1395nn(a)(1)(A).

⁶ 42 U.S.C. § 1395nn(a)(1)(B).

⁷ CMS intended to address the interplay between the Stark Law’s self-referral prohibition and the Medicaid program in the Phase II Regulations. 69 Fed. Reg. at 16055. With one small exception, however, CMS decided to “reserv[e] the Medicaid issue for a future rulemaking” in the “interest of expediting publication” of the Phase II Regulations. 69 Fed. Reg. at 16055.

- Principal Elements (Section IV).
- Exceptions - Overview (Section V).
- Ownership Interest Exceptions (Section VI).
- Compensation Arrangement Exceptions (Section VII).
- All-Purpose Exceptions (Section VIII).
- Grace Period (Section IX).
- Reporting Requirements (Section X).
- Sanctions (Section XI).

III. Basic Definitions

A. “Designated Health Services”

Only referrals to an entity for the furnishing of “designated health services” implicate the Stark Law. For the most part, CMS did not modify the definitions and interpretations of DHS adopted in the Phase I Regulations. There are a few exceptions, however. For example, in the Phase I Regulations, CMS took the position that “there is no reason to treat lithotripsy any differently than other inpatient or outpatient hospital services.”⁸ In 2002, however, in American Lithotripsy Society v. Thompson, a federal court ruled that lithotripsy did not constitute DHS.⁹ In the Phase II Regulations, CMS concedes, stating that it “will not consider lithotripsy an ‘inpatient or outpatient service’ for purposes of” the Stark Law.¹⁰

In the Phase I Regulations, CMS also took the position that radiology and other imaging services integral to and performed during non-radiology procedures (e.g., an ultrasound used to provide guidance for biopsies) are not DHS, but that radiology or other imaging services performed before a non-radiology procedure (e.g., a chest x-ray before a lung cancer resection) are DHS.¹¹ In the Phase II Regulations, CMS modifies its position, indicating that “radiology services performed immediately after a procedure in order to confirm the placement of an item

⁸ 66 Fed. Reg. 856, 940 (January 4, 2001).

⁹ 215 F. Supp.2d 23, 36 (D.D.C. July 12, 2002).

¹⁰ 69 Fed. Reg. at 16106.

¹¹ 66 Fed. Reg. at 929.

during the procedure are not DHS.”¹²

B. “Physician,” “Immediate Family Member” & “Entity”

Only referrals by “physicians” to an “entity” with which the physician or an “immediate family member” has a financial relationship implicate the Stark Law. CMS has not materially modified the definitions of “physician,” “immediate family member” or “entity.” CMS did expand the term “referring physician,” however, to cover both the physician who makes or directs a referral and his or her solely-owned professional corporation.¹³

C. “Volume or Value”/“Other Business Generated”

A number of Stark Law exceptions require that in order for the financial relationship in question to be protected, the remuneration at issue cannot be based on the “volume or value” of the physician’s referrals or “other business generated” between the parties. The Phase II Regulations make a few changes to CMS’ definitions of these terms.

In the Phase I Regulations, CMS stated that the volume or value standard would not be implicated solely because a compensation arrangement requires a physician to refer to a particular provider.¹⁴ So long as the payment at issue is fixed in advance, is consistent with fair market value, and “otherwise complies with the requirements of the applicable exception,” the fact that an employer, for example, “requires referrals to certain providers will not vitiate the exception.”¹⁵

In response to complaints that its interpretation was “overly broad and could permit required referrals beyond those that are reasonable and appropriate,” CMS has clarified that this provision “applies only to employment, managed care, and personnel services arrangements.”¹⁶ Further, this provision applies only if (1) “the required referrals relate solely to the physician’s services covered under the arrangement” and (2) “the referral requirement is reasonably necessary to effectuate the legitimate purposes of the compensation relationship.”¹⁷ Thus, for example, an entity that employs a physician on a part-time basis to provide services to

¹² 69 Fed. Reg. at 16103.

¹³ 69 Fed. Reg. at 16131.

¹⁴ 66 Fed. Reg. at 877.

¹⁵ 66 Fed. Reg. at 877.

¹⁶ 69 Fed. Reg. at 16068-69.

¹⁷ 69 Fed. Reg. at 16068-69.

the entity cannot condition the employment on “referrals of the physician’s private practice business.”¹⁸

Finally, in the Phase I Regulations, CMS took the position that the term “other business generated” meant that “affected payments cannot be based or adjusted in any way on referrals of DHS or any other business referred by the physician, including other Federal and private pay business.”¹⁹ In the Phase II Regulations, CMS clarifies that “other business generated” does not include any services personally performed by the referring physician.²⁰

D. “Set In Advance”

A number of the exceptions also require the remuneration flowing from the entity furnishing DHS to the physician at issue to be “set in advance.” With one principal exception, CMS does not materially modify its definition of this term. In the Phase I Regulations, CMS took the position that percentage-based payments “do not meet the requirement that compensation be fixed in advance” because such payments are neither “aggregate fixed compensation amounts, nor ‘per service,’ ‘per use,’ or ‘per time period’ payment amounts.”²¹ Shortly before the effective date of the Phase I Regulations, however, CMS decided to reconsider its position.²² In the Phase II Regulations, CMS concedes that its “original position was overly restrictive,” and has modified the “set in advance” definition to permit percentage compensation arrangements provided the formula at issue is “established with specificity prospectively,” is “objectively verifiable,” and is not “changed over the course of the agreement . . . based on the volume or value of referrals or other business generated by the referring physician.”²³

E. “Fair Market Value”

A number of Stark Law exceptions require that the remuneration at issue reflect “fair market value.” For the most part, CMS leaves the definition of this term unchanged. The Phase II Regulations do, however, provide that an hourly payment for a physician’s personal services “shall be considered to be fair market value” if (1) the hourly rate “is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market” or

¹⁸ 69 Fed. Reg. at 16069-70.

¹⁹ 66 Fed. Reg. at 877.

²⁰ 69 Fed. Reg. at 16068.

²¹ 66 Fed. Reg. at 878.

²² 66 Fed. Reg. 60154, 60155 (Dec. 3, 2001).

²³ 69 Fed. Reg. at 16068.

(2) the hourly rate “is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice)” in at least four of six specified surveys.²⁴

F. “Group Practice”

Several Stark Law exceptions require the existence of a “group practice.” With a few exceptions, CMS does not materially modify its definition of this term. The Phase I Regulations provided that a group practice must consist of a single legal entity.²⁵ In response to comments concerning how this rule applies to a group practice with offices in more than one State, the Phase II Regulations provide that if both entities are identical “as to ownership, governance, and operation, the States in which the group is operating are contiguous, and the group uses multiple legal entities solely to comply with jurisdictional licensing laws,” CMS “will consider the two entities to be a single legal entity.”²⁶

The Phase I Regulations also established a 12-month “grace period” for start-up groups to come into compliance with the group practice definition. CMS excluded existing group practices that add new members from the grace period to “ensure that groups would not . . . secure perpetual grace periods through the continuing addition of new physicians.”²⁷ CMS changed its position in the Phase II Regulations, providing that “if the addition of a new member who has relocated his or her practice to an existing group practice would cause the group practice to fall out of compliance with” certain group practice definition requirements, then “the group practice will have 12 months to come back into full compliance,” provided certain additional conditions are met.²⁸

Finally, the Phase I Regulations required that a group practice operate as a “unified business.” In order to qualify as a unified business, CMS required that the putative group practice engage in “centralized utilization review.”²⁹ In response to comments that many group practices simply do not perform utilization review, centrally or otherwise, CMS has deleted this

²⁴ 69 Fed. Reg. at 16128.

²⁵ 42 C.F.R. § 411.352(a).

²⁶ 69 Fed. Reg. at 16076

²⁷ 69 Fed. Reg. at 16078.

²⁸ 69 Fed. Reg. at 16078.

²⁹ 42 C.F.R. § 411.352(f)(1).

requirement.³⁰

IV. Principal Elements

To determine whether a particular arrangement involves referrals that violate the Stark Law, the following questions must be answered:

- Will the physician be making “referrals”?
- If so, will the referrals be “to” an entity?
- If so, will this entity be “furnishing” DHS?
- If so, do the physician and entity have a “financial relationship”?

If the answer to all of these questions is “yes,” then the Stark Law will be implicated and, if no exception applies, violated.

A. “Referral”

The first step in analyzing an arrangement under the Stark Law is determining whether a physician has made a “referral.” A physician makes a “referral” any time he or she (1) “requests” an item or service that is payable by Medicare Part B or (2) “requests” or establishes a plan of care that includes DHS.³¹

In the Phase I Regulations, CMS excluded from the definition of “referral” DHS that are personally furnished by the requesting physician.³² A number of commenters urged CMS to go further and exclude services furnished “incident to” a physician’s personally performed services and services furnished by a physician’s employees.³³ CMS declined, noting that a “blanket exclusion” of the type proposed would, among other things, “substantially swallow the in-office ancillary services exception.”³⁴ CMS also reiterated that although “no referral occurs when a physician personally performs services in a hospital,” the “technical components associated with a physician’s personally performed services in a hospital are referrals” for purposes of the Stark

³⁰ 69 Fed. Reg. at 16080.

³¹ 42 U.S.C. § 1395nn(h)(5)(A)-(B).

³² 42 C.F.R. § 411.351.

³³ 69 Fed. Reg. at 16063.

³⁴ 69 Fed. Reg. at 16063.

Law.³⁵

The Stark Law also provides that the term “referral” does not include the request by a radiation oncologist for radiation therapy, provided (1) the request is pursuant to a request by another physician for a “consultation” and (2) the radiation therapy is personally performed by the oncologist or by someone under his or her supervision.³⁶ CMS expanded the definition of “radiation therapy” in the Phase II Regulations to include other DHS furnished as part of radiation therapy treatment, such as computerized axial tomography, magnetic resonance imaging, and ultrasound services, on the ground that these are “often integral and necessary to the provision of radiation therapy.”³⁷

B. “To”

The next question is whether the physician has made a referral “to” an entity for the furnishing of DHS. In the 1998 Proposed Regulations, CMS stated that it would “presume” that a physician had made a referral “to” an entity whenever any of his or her Medicare patients received DHS from an entity with which the physician had a financial relationship.³⁸ CMS modified its position somewhat in the Phase I Regulations, stating that, at a minimum, there needed to be some element of patient “direction or steering” before a physician could be said to have referred a patient “to” an entity.³⁹ For example, “when a physician provides an order or prescription for a DHS to a patient that ostensibly can be filled by any of a number of entities and then suggests or informs the patient that the order can be serviced by a particular entity, there would be a referral ‘to’ that entity.”⁴⁰

CMS revisits this issue in the Phase II Regulations, observing that the Stark Law

embodies a congressional determination to discourage physicians from having financial relationships with DHS entities to which they refer Medicare patients. Neither the statute nor the regulations burdens any physician-patient communications except those communications in which the physician refers to those DHS

³⁵ 69 Fed. Reg. at 16063.

³⁶ 42 U.S.C. § 1395nn(h)(5)(C); 42 C.F.R. § 411.351.

³⁷ 69 Fed. Reg. at 16065.

³⁸ 63 Fed. Reg. 1659, 1711 (January 9, 1998).

³⁹ 66 Fed. Reg. at 873.

⁴⁰ 66 Fed. Reg. at 873 (emphasis added).

entities with which the physician has a prohibited financial relationship. Although disclosure of financial interests to patients informs patients of the potential conflict of interest, we do not believe, nor does the statute contemplate, that such disclosure adequately protects against improper referrals or overutilization. If DHS entities and physicians insist on entering into financial relationships, they can protect themselves by structuring the relationships to fit in one of the exceptions.⁴¹

Thus, although not entirely clear, it would appear that CMS takes the position that where (1) a physician provides an order or prescription for DHS to a patient, (2) that order or prescription can be filled by a number of different suppliers, (3) the physician discloses to the patient that the physician owns one of the suppliers, (4) the physician does not recommend or otherwise suggest that the patient actually utilize that supplier, and (5) the patient ultimately uses the physician-owned supplier, a referral has been made by the physician “to” that supplier for Stark Law purposes.

C. “Furnishing”

The next question is whether the entity at issue is, in fact, “furnishing” DHS. Under the Phase I Regulations, an entity is deemed to be “furnishing” DHS if it is the entity to which CMS makes payment for the DHS.⁴² The Phase II Regulations do not materially alter this definition.

D. “Financial Relationship”

The next step is determining whether a physician (or family member) has a “financial relationship” with the entity furnishing DHS. This “financial relationship” may take the form of (1) a direct or indirect ownership or investment (“ownership”) interest in the entity or (2) a direct or indirect compensation arrangement with the entity.

With respect to direct ownership and direct compensation arrangements, CMS reconsidered its earlier decision to treat stock options and convertible securities as ownership interests. Under the Phase II Regulations, the treatment of options and convertible securities will now depend on the method of acquisition: options and securities acquired in return for money or other capital will be considered “ownership interests;” those received as compensation for services will give rise to a “compensation arrangement” (until such time as they are exercised or converted to equity).⁴³

⁴¹ 69 Fed. Reg. at 16064.

⁴² 42 C.F.R. § 411.351.

⁴³ 69 Fed. Reg. at 16062-63.

The bulk of the comments focused on the somewhat confusing, but pivotal, interplay between the definition of an “indirect compensation arrangement” and the exception for “indirect compensation arrangements.”⁴⁴ Under the bright line test established by the Phase I Regulations, an indirect compensation arrangement exists if three conditions are met.

- First, there must be an “unbroken chain” of financial relationships (ownership or compensation) between the referring physician and the DHS entity.⁴⁵ This condition is satisfied, for example, where a lab furnishes services to a hospital on a per procedure basis and the lab also pays a physician \$120 per hour to serve as the lab’s medical director. Because there is an unbroken chain of financial relationships between the physician and the hospital, the physician may have an indirect compensation arrangement with the hospital. (Importantly, CMS takes the position that this would be true even if each of the financial arrangements in the chain — i.e., the Hospital-Lab arrangement and the Lab-Physician arrangement — qualifies for an exception.⁴⁶)
- Second, the physician’s aggregate compensation (e.g., the lab’s \$120 per hour payment to the physician) must vary with, or otherwise reflect, the volume or value of referrals or other business generated by the referring physician for the entity at issue (e.g., the hospital).⁴⁷ Because the “special rules on compensation” provide that unit-based compensation does not to trigger the “volume or value” standard, commenters questioned whether such an arrangement could ever give rise to an indirect compensation arrangement.⁴⁸ CMS acknowledged that the “similarity” between the volume or value standard used in the definition of “indirect compensation arrangement” and in the special compensation rules was a source of confusion that warranted clarification.⁴⁹ In the Phase II Regulations, CMS takes the position that unit-based compensation arrangements may implicate the “volume or value” standard for purposes of the second prong of the definition of indirect

⁴⁴ 69 Fed. Reg. at 16058.

⁴⁵ 42 C.F.R. § 411.354(c)(2)(i).

⁴⁶ 69 Fed. Reg. at 16059.

⁴⁷ 42 C.F.R. § 411.354(c)(2)(ii).

⁴⁸ 69 Fed. Reg. at 16058.

⁴⁹ 69 Fed. Reg. at 16059.

compensation arrangement.⁵⁰ CMS hastens to add, however, that such arrangements satisfy the special compensation rules and, as such, do not trigger the “volume or value” standard for purposes of any exception, including, but not limited to, the exception for “indirect compensation arrangements.”⁵¹

- Third, the DHS entity must have actual knowledge (or must act in reckless disregard or deliberate ignorance) of the fact that the referring physician’s aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity. This requirement remains unchanged.⁵²

The Phase II Regulations address two other matters of note related to indirect financial arrangements:

- As discussed briefly above, the definition of “referring physician” has been expanded to include a physician’s wholly-owned professional corporation.⁵³ Thus, a financial arrangement between a medical professional corporation (that is wholly-owned by a single physician) and a furnishing entity will give rise to a direct financial arrangement between the physician and the entity, but not an indirect one.
- CMS has clarified that common ownership of an entity does not give rise to an indirect ownership interest between the common owners. Such an arrangement has the potential to give rise to an indirect compensation arrangement, however.

V. Exceptions Generally

Even where a physician’s referrals trigger all of the Stark Law’s elements, such referrals will be permitted if the arrangement at issue fits within an Ownership Interest, Compensation Arrangement, or All Purpose Exception. As noted above:

⁵⁰ 69 Fed. Reg. at 16058.

⁵¹ 69 Fed. Reg. at 16059.

⁵² 69 Fed. Reg. at 16059.

⁵³ 69 Fed. Reg. at 16060.

- Prior to issuance of the Phase I Regulations in 2001, there were a total of 16 exceptions: three Ownership Interest Exceptions, nine Compensation Arrangement Exceptions, and four All-Purpose Exceptions.
- The Phase I Regulations added six new Compensation Arrangement Exceptions and five new All-Purpose Exceptions.
- The Phase II Regulations add six more Compensation Arrangement Exceptions and one more All Purpose Exception. (The Phase II Regulations also delete one All Purpose Exception.)

Thus, upon the effective date of the Phase II Regulations, there will be a total of 33 exceptions: three Ownership Interest Exceptions, 21 Compensation Arrangement Exceptions, and nine All-Purpose Exceptions. These are addressed in Sections VI, VII and VIII below.

VI. Ownership Interest Exceptions

A. Publicly Traded Securities & Mutual Funds

Although the Phase II Regulations largely leave these two exceptions unchanged, CMS has relaxed its interpretation of the phrase, "may be purchased on terms generally available to the public . . . to mean that the ownership interest must be in securities that are generally available to the public at the time of the DHS referral" rather than at the time the securities were obtained.⁵⁴ Thus, securities acquired prior to a public offering will be protected as long as they are available to the public at the time of any DHS referral.⁵⁵ The Phase II Regulations also eliminate the reporting requirement for shareholder information regarding financial relationships that satisfy these two exceptions.⁵⁶

B. Specific Providers

The Stark Law has three "specific provider" exceptions: ownership in rural providers ("Rural Provider Exception"),⁵⁷ ownership in hospitals located in Puerto Rico ("Puerto Rico Hospital Exception"),⁵⁸ and ownership in other hospitals ("Other Hospital Exception").⁵⁹ With a

⁵⁴ 69 Fed. Reg. at 16081.

⁵⁵ 69 Fed. Reg. at 16081.

⁵⁶ 69 Fed. Reg. at 16082.

⁵⁷ 42 U.S.C. § 1395nn(d)(2).

⁵⁸ 42 U.S.C. § 1395nn(d)(1).

few exceptions, the Phase II Regulations largely adopt the Proposed Rule.

CMS conforms the Other Hospital Exception to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA"), implementing an 18-month moratorium on the referral of Medicare patients to certain "specialty hospitals," subject to certain grandfathering provisions.⁶⁰ CMS also clarifies that the Rural Provider Exception will not protect ownership in "specialty hospitals" during the 18-month moratorium.⁶¹ Finally, although CMS refused to "grandfather" investments in rural areas that are later reclassified as non-rural areas, CMS did clarify that the new grace period for certain arrangements that inadvertently and temporarily fall out of compliance with an exception (discussed in Section IX below) might be available under such circumstances.⁶²

VII. Compensation Arrangement Exceptions

A. Original (Pre-Phase I) Compensation Arrangement Exceptions

1. Rental of Office Space and Equipment

The Phase II Regulations differ in several respects from the Proposed Rule with respect to the office space and equipment rental exceptions. First, CMS has liberalized the requirement that the term of the lease at issue be for at least one year, stating that this requirement will be met even if the lease may be terminated by either party without cause (provided the parties do not enter into a new lease during the remainder of the first year of the term).⁶³ In addition, month-to-month holdover provisions will not negate compliance with the one year term requirement (provided the original terms of the underlying lease continue through the monthly tenancy and the holdover period does not exceed six months).⁶⁴

Footnote continued from previous page

⁵⁹ 42 U.S.C. § 1395nn(d)(3).

⁶⁰ 69 Fed. Reg. at 16084. See also "Physician Self-Referral Prohibition; 18-Month Moratorium on Physician Investment in Specialty Hospitals," Pub. No. 100-20, Transmittal No. 62 (March 19, 2004).

⁶¹ 69 Fed. Reg. at 16082.

⁶² 69 Fed. Reg. at 16083.

⁶³ 69 Fed. Reg. at 16086.

⁶⁴ 69 Fed. Reg. at 16086.

CMS also expanded the category of leases eligible for protection under these exceptions. In contrast to the Proposed Rule, which covered only operating leases, the exceptions are now available to any bona fide lease arrangement, including capital leases.⁶⁵ Finally, CMS eased its interpretation of the requirement that the leased space or equipment be “used exclusively by the lessee.”⁶⁶ Under the Phase II Regulations, many sublease arrangements may now meet the requirement of the lease exceptions, provided the lessee (or sublessee) does not share the rented space or equipment with the lessor during the time it is rented or used by the lessee (or sublessee).⁶⁷

2. Bona Fide Employment Relationships

The bona fide employment relationships exception in the Phase II Regulations largely tracks the Proposed Rule. There are a few exceptions, however. For example, the exception now clearly permits physician-employees to be paid a productivity bonus based on personally furnished DHS.⁶⁸ (Bonuses based on “incident to” DHS are still prohibited, however.)⁶⁹ In addition, although employers may continue to restrict their employee’s referrals, such restrictions are subject to several additional limitations. See Section II.C. above.

3. Personal Service Arrangements

With a few exceptions, CMS largely adopts the provisions of the personal services arrangement exception set forth in the Proposed Rule. First, as with lease arrangements, CMS clarifies that the one year term requirement is not violated as a result of a termination without cause provision as long as the parties do not enter into the same (or substantially the same) arrangement during the first year of the original term.⁷⁰ Second, CMS clarifies that payments from downstream subcontractors (and not just health maintenance organizations and other entities enrolling patients) are included in the physician incentive plan exception.⁷¹

Third, the Phase II Regulations ease the requirement that a personal services

⁶⁵ 69 Fed. Reg. at 16086.

⁶⁶ 69 Fed. Reg. at 16138.

⁶⁷ 69 Fed. Reg. at 16086.

⁶⁸ 69 Fed. Reg. at 16138.

⁶⁹ 69 Fed. Reg. at 16087.

⁷⁰ 69 Fed. Reg. at 16090.

⁷¹ 69 Fed. Reg. at 16090.

agreement cover all of the services to be furnished by the physician. This requirement may now be satisfied if all separate arrangements between the entity and the physician (1) incorporate each other by reference or (2) "cross reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request."⁷²

Fourth, CMS also rejected an earlier proposal that would have precluded items or equipment from being included in an arrangement under the personal services arrangement exception. According to CMS, the proposed "exclusivity rule" was "unnecessarily formalistic."⁷³ Finally, CMS clarifies that a physician may furnish personal services under the exception through (1) employees hired for the purpose of performing such services, (2) through a wholly owned entity, or (3) through *locum tenens* physicians.⁷⁴

4. Physician Recruitment

The Phase II Regulations substantially revise the recruitment exception and add a new exception for certain retention payments by hospitals and federally qualified health centers (discussed in Section VII.C.5. below). At bottom, the exception is predicated on a physician's agreement — in return for remuneration from a hospital — to "relocate" to "the geographic area served by the hospital."⁷⁵ The highlights of the revised exception are set forth below:

- Having invited public comment on how to define the relevant "geographic area," CMS adopts a bright line test: "geographic area served by the hospital" now means the "area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of all its inpatients."⁷⁶ (It is unclear whether arrangements that were based on a different geographic area will have to be restructured.)
- The term "relocation" also has been defined for the first time. Relocation requires the physician (1) to move his or her medical practice (but not necessarily his or her residence) a minimum of 25 miles or (2) to establish a substantial base of new patients (i.e., at least 75 percent of the physician's professional services revenue must derive from services

⁷² 69 Fed. Reg. at 16091.

⁷³ 69 Fed. Reg. at 16090-91.

⁷⁴ 69 Fed. Reg. at 16090, 16093.

⁷⁵ 69 Fed. Reg. at 16139.

⁷⁶ 69 Fed. Reg. at 16095.

furnished to patients not seen or treated by the physician in the previous three years).⁷⁷

- Whereas the Proposed Rule suggested that the exception may not cover payments to retain medical residents and new physicians already in a hospital's geographic area,⁷⁸ the Phase II Regulations expressly cover the recruitment of medical residents and new physicians (i.e., those who have been in practice less than one year), exempting them from the relocation requirement discussed above.⁷⁹
- The applicability of the Proposed Rule to group practice relocations was not entirely clear.⁸⁰ The new Phase II Regulations permit hospitals to provide financial support for recruitment through an existing medical group, provided, among other things that: (1) the arrangement is set forth in a written agreement signed by the party to whom payments are directly made, (2) all remuneration (minus actual costs incurred) must be passed through to (or remain with) the recruited physician, and (3) in the event of an income guarantee, the costs allocated to the recruited physician cannot exceed the actual additional incremental costs attributable to him or her.⁸¹ (CMS also imposes a five year record retention requirement with respect to documents reflecting costs and pass-through amounts.⁸²)

According to CMS, the revised exception protects the remuneration (1) between the sponsoring hospital and the recruited physician and (2) between the sponsoring hospital and the host medical practice, where relevant.⁸³ CMS' position with respect to the latter issue is confusing, because the Stark Law addresses "physician" referrals, and not "practice group"

⁷⁷ 69 Fed. Reg. at 16095.

⁷⁸ 63 Fed. Reg. 1659, 1702 (January 9, 1998) ("We believe that . . . this exception applies just to those situations in which a physician resides outside the geographic area and must actually relocate in order to join the hospital's staff.").

⁷⁹ 69 Fed. Reg. at 16095.

⁸⁰ See, e.g., 63 Fed. Reg. at 1702 ("Section 1877(e)(5) includes an exception for remuneration provided to an individual physician . . .").

⁸¹ 69 Fed. Reg. at 16096.

⁸² 69 Fed. Reg. at 16139.

⁸³ 69 Fed. Reg. at 16097.

referrals. Further, given CMS' repeated statements that excepted financial relationships may still give rise to an indirect compensation arrangement, in the host practice relocation context, hospitals will need to be careful to avoid creating indirect compensation arrangements with non-recruited physicians who are affiliated with a recruiting medical practice.

5. Isolated Transactions

The isolated transactions exception has been changed in two principal (and practical) respects. First, an "isolated transaction" is no longer limited to a single payment. Rather, the Phase II Regulations permit integrally related installment payments if two conditions are met: the total aggregate payment must be fixed before the first payment is made and may not take into account the volume or value of referrals or other business generated by the referring physician; and the payments must be immediately negotiable or (1) guaranteed by a third party, (2) secured by a negotiable promissory note, or (3) subject to a similar mechanism to ensure payment in the event of default or bankruptcy.⁸⁴ Second, post-closing adjustments to the purchase price (e.g., escrows, reconciliation of accounts receivable, and the like) and some other commercially reasonable compensation is permitted if made within six months of the date of the transaction.⁸⁵

6. Remuneration Unrelated to the Provision of DHS

Under the Phase II Regulations, this exception is now very narrow and available only where the remuneration at issue is "wholly unrelated" to the provision of DHS.⁸⁶ Remuneration is not "wholly unrelated" to the furnishing of DHS if it (1) "is an item, service, or cost that could be allocated . . . to Medicare or Medicaid under cost reporting principles," (2) "is furnished . . . in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals," or (3) "otherwise takes into account the volume or value of referrals or other business generated by the referring physician."⁸⁷ Thus, for example, payments to support malpractice insurance or for a covenant not to compete are related to the provision of DHS.⁸⁸ Consistent with these limitations, CMS has withdrawn its earlier position that general administrative or utilization review services are not related to DHS.⁸⁹ Finally,

⁸⁴ 69 Fed. Reg. at 16098.

⁸⁵ CITE.

⁸⁶ 69 Fed. Reg. at 16093.

⁸⁷ 42 C.F.R. § 411.357(g)(1)-(3).

⁸⁸ 69 Fed. Reg. at 16094.

⁸⁹ 69 Fed. Reg. at 16094.

although a payment that is wholly unrelated to the provision of DHS does not have to be fair market value for the exception to apply, CMS states that it will carefully scrutinize any payments above fair market value to ensure that they are not, in fact, disguised payments related to DHS.⁹⁰

7. Certain Group Practice Arrangements With a Hospital

The Phase II Regulations do not materially modify this exception, which protects a very narrow set of arrangements between a hospital and a medical practice pursuant to which the hospital bills for services furnished by the practice.⁹¹ To qualify, the arrangements must have been commenced prior to December 19, 1989 and must have remained in effect (without interruption) since then.⁹²

8. Payments by a Physician for Items and Services

For the most part, CMS adopts this exception, which covers physician payments to clinical labs and other entities for items and services, provided such payments are consistent with fair market value.⁹³ Notably, however, CMS modifies and/or interprets the exception to make it clear that the exception covers payments (1) by immediate family members,⁹⁴ (2) for items or services of any kind (and not just those covered by Medicare),⁹⁵ and (3) for items and services purchased at a “legitimate discount” (obviating the need for a separate exception for discounts, as provided for in the Proposed Rule).⁹⁶ Finally, CMS makes it clear in the Phase II Regulations that this exception is unavailable for items or services that are specifically covered by another exception.⁹⁷ Thus, for example, this exception will not protect payments that a physician (or an immediate family member) makes to his or her landlord for leased premises.⁹⁸

⁹⁰ 69 Fed. Reg. at 16094.

⁹¹ 69 Fed. Reg. at 16140

⁹² 69 Fed. Reg. at 16140.

⁹³ 69 Fed. Reg. at 16099.

⁹⁴ 69 Fed. Reg. at 16099.

⁹⁵ 69 Fed. Reg. at 16099.

⁹⁶ 69 Fed. Reg. at 16099 (referring to the exception originally proposed for 42 C.F.R. § 411.357(j)).

⁹⁷ 69 Fed. Reg. at 16099.

⁹⁸ 69 Fed. Reg. at 16099.

B. Compensation Arrangement Exceptions Created in Phase I Regulations

1. Compensation Under \$300 Per Year

The Phase I Regulations created an exception for non-monetary compensation that does not exceed \$300 per year.⁹⁹ In the Phase II Regulations, CMS rejected commenters' requests to increase this \$300 limit. The agency did, however, agree to adjust the limit annually to keep up with inflation.¹⁰⁰

2. Fair Market Value Compensation

Pursuant to the Phase I Regulations, any compensation paid by an entity to a physician (or group of physicians) in exchange for items or services does not constitute a "financial relationship" for purposes of the Stark Law provided the compensation is fair market value, the arrangement is set forth in a written agreement, and certain other conditions are met. Several commenters asked CMS to expand this exception to include other types of physician-provider arrangements, including those involving (1) the transfer, lease or license of real or intangible property and (2) covenants not to compete.¹⁰¹ CMS declined this invitation, stating that other Stark Law exceptions adequately address these types of arrangements.¹⁰²

3. Medical Staff Incidental Benefits

Recognizing that many hospital medical staff privileges — such as free parking — do not pose a material risk of overutilization or other program abuse,¹⁰³ the Phase I Regulations created an exception for certain incidental benefits provided by hospitals to members of their medical staffs.¹⁰⁴ The Phase II Regulations modify this exception as follows: (1) benefits no longer have to be commensurate with those offered by other hospitals; (2) Internet access, pagers or two-way radios that are used away from the hospital campus to access hospital medical records, information, and patients or personnel that are on the hospital campus will meet the exception's "on-campus" requirement; (3) benefits may be provided while the physician is "engaged in other services or activities" in contrast to "performing duties" that

⁹⁹ 42 C.F.R. § 411.357(k).

¹⁰⁰ 69 Fed. Reg. at 16112.

¹⁰¹ 69 Fed. Reg. at 16111.

¹⁰² 69 Fed. Reg. at 16111.

¹⁰³ 66 Fed. Reg. at 921.

¹⁰⁴ 42 C.F.R. § 411.357(m).

benefit the hospital; (4) the \$25 limit will be indexed for inflation; and (5) the exception may be relied upon by all facilities that have a *bona fide* medical staff.¹⁰⁵

4. Risk Sharing Arrangements

The Phase I Regulations created an exception that protects certain compensation exchanged between a managed care organization or an independent physicians association and a physician (either directly or through a subcontractor) for the furnishing of services to enrollees of a health plan.¹⁰⁶ This exception is unchanged by the Phase II Regulations.

5. Compliance Training

Recognizing the importance of compliance programs — and the fact that the provision of such programs might create a compensation arrangement — the Phase I Regulations created an exception for such programs. Pursuant to this exception, compensation for purposes of the Stark Law does not include compliance training offered by a hospital to physicians who practice in the hospital’s local community or service area, provided that the training is offered in the local community or service area.¹⁰⁷ In response to several comments, CMS has expanded this exception in the Phase II Regulations to include (1) compliance training offered by any DHS entity (and not just hospitals) and (2) the provision of compliance training to a physician’s immediate family members and office staff.¹⁰⁸

6. Indirect Compensation Arrangements

The Phase I Regulations established a new exception for indirect compensation arrangements.¹⁰⁹ In order for this exception to apply, three conditions must be met. First, the compensation must be consistent with the “fair market value,” “volume or value,” and “other business generated” standards.¹¹⁰ (It is unclear how CMS intends to apply this condition where the referring physician’s immediate financial relationship in the “unbroken chain” of financial relationships is an ownership interest. This is particularly true where the physician at issue does not provide any items or services to the entity in which the physician has an ownership interest.)

¹⁰⁵ 69 Fed. Reg. at 16141.

¹⁰⁶ 69 Fed. Reg. at 16141.

¹⁰⁷ 42 C.F.R. § 411.357(o).

¹⁰⁸ 69 Fed. Reg. at 16141.

¹⁰⁹ 42 C.F.R. § 411.357(p).

¹¹⁰ 42 C.F.R. § 411.357(p)(1).

Second, with the exception of employment arrangements, the compensation arrangement in the “unbroken chain” of financial relationships must be set out in writing, be signed by the parties, and specify the services covered by the arrangement.¹¹¹ Third, the arrangement must not violate the Anti-Kickback Law or any other law governing Medicare billing or claims submissions.¹¹² As discussed in Section IV.D. above, the Phase II Regulations explain the differences and interplay between this exception and the related indirect compensation arrangement test.

C. Compensation Arrangement Exceptions Created in Phase II Regulations

1. Charitable Donations By Physicians

Under this new exception, a physician may make a *bona fide* charitable donation to a DHS entity without violating the Stark Law, provided that the donation (1) is made to a tax-exempt organization, (2) is neither solicited nor made in a manner that takes into account the volume or value of referrals or other business generated between the parties, and (3) does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.¹¹³

2. Referral Services

For purposes of this exception, CMS incorporated by reference the anti-kickback law’s referral services safe harbor.¹¹⁴ Accordingly, in order to apply, this exception requires that the referral service (1) not exclude as a participant any individual or entity that meets the service’s qualification requirements, (2) not impose requirements on participants regarding the manner in which services are provided to a referral (except that the service may require that referrals are charged the same rate as other persons), and (4) make certain disclosures to those seeking a referral.¹¹⁵ In addition, the payments to participate in the referral service must be assessed and collected equally.¹¹⁶

¹¹¹ 42 C.F.R. § 411.357(p)(2).

¹¹² 42 C.F.R. § 411.357(p)(3).

¹¹³ 69 Fed. Reg. at 16140.

¹¹⁴ 69 Fed. Reg. 16114.

¹¹⁵ 69 Fed. Reg. at 16115.

¹¹⁶ 69 Fed. Reg. at 16115.

3. Obstetrical Malpractice Insurance

Under this new exception, a hospital (or other entity) may pay a medical malpractice insurer for some or all of the premiums for an ob-gyn physician who practices in a HPSA, provided certain conditions are satisfied.¹¹⁷ In any other context, payment to support a physician's malpractice premiums will give rise to a financial relationship.

4. Professional Courtesy

In recognition of the longstanding and widespread practice among hospitals and group practices of providing free or reduced cost health care items and services to physicians and their immediate family members, CMS establishes a new, fairly broad exception for certain "professional courtesies."¹¹⁸ Among other things, the exception permits the extension of courtesies to members of a physician's office staff.¹¹⁹

5. Retention Payments in Underserved Areas

Although CMS historically has been wary of payments by hospitals to "retain" physicians within their geographic area, it has relented with respect to payments made by a hospital or a federally qualified health center ("FQHC") to a physician (1) whose practice is located in a HPSA (regardless of the physician's specialty) or in an area with a demonstrated need for the physician's specialty and (2) who has received a bona fide written recruitment offer from a hospital (or FQHC) located outside of the geographic area at issue.¹²⁰ Among other things, the new exception regulates both the amount and frequency of such retention payments.¹²¹

6. Community-Wide Health Information Systems

In an effort to improve health at a community-wide level, CMS has created an exception for information technology (hardware and software) that is provided to a physician to permit him or her to access and participate in a community-wide health information system available to all providers, practitioners, and residents in the community.¹²² The exception contemplates a

¹¹⁷ 69 Fed. Reg. at 16115.

¹¹⁸ 69 Fed. Reg. at 16115.

¹¹⁹ 69 Fed. Reg. at 16116.

¹²⁰ 69 Fed. Reg. at 16097.

¹²¹ 69 Fed. Reg. at 16097.

¹²² 69 Fed. Reg. at 16113.

system that affords access to electronic health care records and facilitates the sharing of medical information and alerts.¹²³

VIII. All Purpose Exceptions

A. Original (Pre-Phase I) All Purpose Exceptions

1. Physician Services

The Stark Law's referral and billing prohibitions do not apply to DHS that take the form of "physician services" and are provided by a physician in the referring physician's group practice.¹²⁴ Although CMS made no modifications to this exception, it clarified that the exception covers the provision of antigens (an outpatient drug) by allergists.¹²⁵

2. In-Office Ancillary Services

The Stark Law's referral and billing prohibitions also do not apply to "in-office ancillary services," provided three requirements — that govern who may furnish the DHS, where the DHS may be furnished, and, finally, who may bill for such DHS — are met.¹²⁶ Under the second requirement (*i.e.*, the location requirement), ancillary services may be furnished in one of two places: a "centralized building" used by a group practice to furnish DHS or the "same building" in which the referring physician (or his or her group) furnishes "physician services unrelated to the furnishing of DHS." In an effort to provide greater flexibility, establish a clearer rule, and reduce potentially abusive practices,¹²⁷ CMS has substantially revised its previous definitions of the terms "same building" and "physician services unrelated to the furnishing of DHS"¹²⁸

¹²³ 69 Fed. Reg. at 16113.

¹²⁴ 42 U.S.C. § 1395nn(b)(1); 42 C.F.R. § 411.355(a).

¹²⁵ 69 Fed. Reg. at 16070.

¹²⁶ 42 U.S.C. § 1395nn(b)(2); 42 C.F.R. § 411.355(b).

¹²⁷ 69 Fed. Reg. at 16072. As an example of such abuse, CMS offers the following scenario. A group practice leases space at an off-site imaging center, provides physician services at that location one day per week, and then provides imaging services at the location for the remainder of the week, without any involvement or presence of the group practice physicians at the site. See 69 Fed. Reg. at 16072.

¹²⁸ CMS previously used a three-part test for determining whether a group provided physician services unrelated to the furnishing of DHS in the same building as the DHS. The

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Specifically, CMS developed three new tests, described below:

- The building is one in which the referring physician or his or her group practice, if applicable, has an office (1) that is normally open to patients at least 35 hours per week and (2) that is regularly used by the physician (or group) to practice medicine and furnish physician services for at least 30 hours per week, some of which must be non-DHS (although these unrelated physician services may lead to the ordering of DHS).
- The building is one in which the referring physician or his or her group practice, if applicable, has an office (1) that is normally open to patients at least 8 hours per week and (2) that is regularly used by the physician (or group) to practice medicine and furnish physician services (including non-DHS services) for at least 6 hours per week. Note that physician services furnished by members of the referring physician's group practice do not count toward the 6-hour requirement. Note also that the building must be the one in which the patient receiving the DHS usually sees the referring physician or a member of his or her group practice for physician services.
- The building is one in which the referring physician or his or her group practice, if applicable, has an office (1) that is normally open to patients at least 8 hours per week and (2) that is regularly used by the physician (or group) to practice medicine and furnish physician services (including physician services that are unrelated to the furnishing of DHS) at least 6 hours per week. In addition, the referring physician must be present in the office and order the DHS in connection with a patient visit in the office or the referring physician (or a member of his group) must be present in the building while the DHS is furnished.¹²⁹

Only one of these three tests must be satisfied to meet the same building requirement, and all three are available to solo practitioners as well as group practices.¹³⁰ Moreover, according to CMS, these tests will accommodate the occasional weeks in which the office is

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physician services had to (1) be neither federal nor private pay DHS, (2) represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides, and (3) be the primary reason for the patient's coming in contact with the referring physician (as opposed to the DHS). 66 Fed. Reg. at 888.

¹²⁹ 42 C.F.R. § 411.354(b)(2)(i).

¹³⁰ 69 Fed. Reg. at 16072.

open fewer hours than required, due to vacations and the like.¹³¹ Note also that each of these tests requires only that “some” (rather than the previous “substantial”) quantum of physician services furnished in the building be unrelated to the furnishing of DHS.¹³² CMS has not defined the term “some,” opting instead to use a “common sense” approach.¹³³ Finally, physician services may be unrelated to furnishing DHS, even if they lead to the ordering of DHS.¹³⁴ Interpretations or reads of tests, however, are generally DHS and, as such, will not count as physician services unrelated to the furnishing of DHS.¹³⁵

3. Services Furnished to Enrollees of Prepaid Plans

The Phase II Regulations expands the exception for DHS furnished to enrollees of certain Medicare prepaid plans to services furnished to analogous Medicaid managed care plans.¹³⁶

4. Certain Clinical Laboratory Services

The Phase II Regulations eliminate the regulatory exception — previously codified at 42 C.F.R. § 411.355(d) — for certain clinical laboratory services. At bottom, the exception was rendered obsolete by the revised definition of DHS set forth in the Phase I Regulations (which excludes services reimbursed by Medicare as part of a composite rate).¹³⁷

B. All Purpose Exceptions Created in Phase I Regulations

1. Academic Medical Centers

The Phase I Regulations established a new exception for DHS furnished by an academic medical center (“AMC”), provided a host of conditions — related to the AMC and the

¹³¹ 69 Fed. Reg. at 16073.

¹³² 69 Fed. Reg. at 16075.

¹³³ 69 Fed. Reg. at 16073.

¹³⁴ 69 Fed. Reg. at 16073.

¹³⁵ 69 Fed. Reg. at 16073.

¹³⁶ 69 Fed. Reg. at 16081.

¹³⁷ See 42 C.F.R. § 411.351.

referring physician, respectively — are met.¹³⁸ CMS appears to have received a fair number of comments concerning this exception, the vast majority of which urged a relaxation of key definitions and requirements. In recognition of “the many variants of the basic academic medical center arrangement[,]”¹³⁹ CMS has tried to accommodate many of these requests. Examples of such accommodation include:

- The expansion of the definition of a qualifying AMC to include a hospital or hospitals that sponsor at least four approved medical education programs (with or without an accredited medical school).¹⁴⁰
- The elimination of the requirement that the relevant faculty plan be organized under either section 501(c)(3) or 501(c)(4) of the Internal Revenue Service Code.¹⁴¹
- The clarification that the referring physician may be an employee of either the medical school (or university) or the hospital.¹⁴²
- The establishment of a “safe harbor” test for ensuring that the referring physician provides “substantial academic or clinical teaching services,” as is required under the exception.¹⁴³

2. Implants (ASC)

The Phase I Regulations exception for the provision of certain implants furnished by an ambulatory surgery center (“ASC”) remains fundamentally unchanged.¹⁴⁴ CMS clarified,

¹³⁸ 42 C.F.R. § 411.355(e). The exception was promulgated in recognition of the unique status of academic medical centers. These centers are typically comprised of multiple affiliated entities that exchange money and referrals, but that do not fit neatly into any of the Stark law’s exceptions. 66 Fed. Reg. at 916.

¹³⁹ 66 Fed. Reg. at 16109.

¹⁴⁰ 42 C.F.R. § 411.355(e)(3).

¹⁴¹ 42 C.F.R. § 411.355(e)(2)(ii).

¹⁴² 42 C.F.R. § 411.355(e)(1)(i)(A),(C).

¹⁴³ 42 C.F.R. § 411.355(e)(1)(i)(D).

¹⁴⁴ 42 C.F.R. § 411.355(f). This exception is important because many implants are DHS, but are not bundled in the ASC composite rate.

however, that the exception applies only if the ASC is the DHS entity.¹⁴⁵ If a physician bills for the implant (and, as such, becomes the DHS entity), another exception must be satisfied.¹⁴⁶

3. Certain Dialysis Related Outpatient Prescription Drugs

The Phase I Regulations created a new exception for EPO and other dialysis related outpatient prescription drugs (collectively, “Dialysis Drugs”), provided certain conditions are met.¹⁴⁷ CMS did not modify this exception in the Phase II Regulations, except to add several additional drugs to the list of Dialysis Drugs, including albumin, levocarnitine, and darbepoetin alfa.¹⁴⁸

4. Preventive Screening, Immunizations, and Vaccines

The Phase I Regulations created a new exception for preventive screening tests, immunizations, and vaccines (collectively, “Preventive Services”) that, among other things, are (1) covered by Medicare and listed on CMS’s web site (as well as in any annual updates published in the Federal Register), (2) reimbursed by Medicare pursuant to a fee schedule, and (3) subject to CMS-mandated frequency limits.¹⁴⁹ In the Phase II Regulations, CMS deleted the second of the three requirements listed above because some of the vaccines covered by the exception may be reimbursed by Medicare using a methodology other than a fee schedule.¹⁵⁰ CMS also reiterated its view that diagnostic mammography does not qualify as a Preventive Service for purposes of this exception.¹⁵¹

5. Eyeglasses and Contact Lenses

The Phase I Regulations created a new exception for eyeglasses and contact lenses that are furnished to Medicare beneficiaries following cataract surgery, provided certain conditions are met.¹⁵² CMS did not modify this exception in the Phase II Regulations.

¹⁴⁵ 69 Fed. Reg. at 16111.

¹⁴⁶ 69 Fed. Reg. at 16111.

¹⁴⁷ 42 C.F.R. § 411.355(g).

¹⁴⁸ 69 Fed. Reg. at 16117.

¹⁴⁹ 42 C.F.R. § 411.355(h).

¹⁵⁰ 69 Fed. Reg. at 16116.

¹⁵¹ 69 Fed. Reg. at 16117.

¹⁵² 42 C.F.R. § 411.355(i).

C. All Purpose Exceptions Created in Phase II Regulations

1. Intra-Family Referrals

The Phase II Regulations create a new (and limited) exception for rural referrals by a physician to his or her immediate family member or to an entity that has a financial relationship with the family member.¹⁵³ The new exception focuses on (1) the location where the services are furnished, not the location of the provider, and (2) the availability of other providers (without regard to their quality) to furnish the services at issue in a timely fashion. Specifically, the exception requires the following:

- the patient must reside in a rural area (an area outside a Metropolitan Statistical Area);
- in the case of services furnished outside of the patient's residence, there is no other DHS entity available to furnish the services in a timely manner in light of the patient's condition within 25 miles of the patient's residence;
- in the case of services furnished to patients where they reside (e.g., home health services, in-home DME), no other DHS entity is available to furnish the services in a timely manner in light of the patient's condition;
- the referring physician or the immediate family member must make reasonable inquiries (e.g., consulting telephone directories, professional associations, other providers and/or internet resources) as to the availability of others to furnish the DHS (located within 25 miles of the patient's residence); and
- the arrangement must not violate the anti-kickback statute and must be billed in a manner that complies with all federal and state laws and regulations.

IX. Grace Period

Several commenters requested a “grace” period for certain arrangements that have “unavoidably and temporarily fallen out of compliance” with an exception.¹⁵⁴ In response, CMS has created a new “quasi”-exception that provides a 90-day period of immunity for certain instances of “temporary noncompliance.”¹⁵⁵ In order to take advantage of this exception,

¹⁵³ 42 C.F.R. § 411.355(j); 69 Fed. Reg. at

¹⁵⁴ 69 Fed. Reg. at 16056-57.

¹⁵⁵ 69 Fed. Reg. at 16057.

however, (1) the financial relationship must have fit within an exception for at least 180 consecutive days prior to the instance of noncompliance, (2) the reasons for the lapse in compliance must be “beyond the control of the entity,” and (3) the entity must promptly take steps to rectify the noncompliance.¹⁵⁶ In addition, this exception may only be used by an entity once every three years with respect to the same referring physician.¹⁵⁷

X. Reporting

The Stark Law requires that each entity furnishing Medicare covered items or services provide the U.S. Department of Health & Human Services (“HHS”) with certain information concerning the entity’s “ownership, investment, and compensation arrangements.”¹⁵⁸ Although HHS is not authorized to waive these requirements, HHS may “gather the information” in such form, manner, and at such times as the agency specifies.¹⁵⁹

In the Proposed Rule, CMS stated that it was “still developing a procedure for implementing the reporting requirements” and thus would not require any reporting until such procedure was put in place.¹⁶⁰ As noted above, although the Phase II Regulations themselves set forth reporting requirements, the related preamble was inadvertently omitted from the March 26, 2004 Federal Register release. Thus, as of the writing of this Article, the precise status of the reporting requirements remains unknown.

However, the Phase II Regulations themselves can be summarized. Like the Phase I Regulations, all entities that furnish more than 20 Part A and Part B services in a calendar year may be required to submit information to CMS or (an addition in the Phase II Regulations) to the HHS Office of Inspector General (“OIG”).¹⁶¹ CMS or the OIG may request the following: (1) the identify of each physician who has a reportable financial relationship with the entity (or who has an immediate family member with such a reportable financial relationship); (2) the covered services furnished by the entity; and (3) the “nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation

¹⁵⁶ 69 Fed. Reg. at 16133.

¹⁵⁷ 69 Fed. Reg. at 16133.

¹⁵⁸ 42 U.S.C. § 1395nn(f).

¹⁵⁹ 42 U.S.C. § 1395nn(f).

¹⁶⁰ 63 Fed. Reg. at 1703.

¹⁶¹ 69 Fed. Reg. at 16142.

arrangement).¹⁶²

The Phase II Regulations include three significant changes with respect to reportable financial relationships. First, the “nature of the financial relationships” to be reported is now limited to those “as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain” to comply with IRS and SEC rules “and other rules of the Medicare and Medicaid programs.”¹⁶³ Second, reportable financial relationships specifically exclude investment interests that satisfy exceptions regarding publicly-traded securities and mutual funds.¹⁶⁴ Third, entities are no longer required to report to CMS annually all changes in the submitted information; instead, entities must “retain” the information for the length of time specified by applicable regulatory requirements and, upon request, must make that information available.¹⁶⁵

Under the Phase II Regulations, entities are to be given at least 30 days from the date of the request to provide the information at issue.¹⁶⁶ As in the Phase I Regulations, any person who fails to report requested information is subject to a CMP of up to \$10,000 for each day the information is not submitted past the due date.¹⁶⁷ Finally, the information furnished to CMS or OIG under this provision is subject to public disclosure in accordance with certain confidentiality and disclosure provisions.¹⁶⁸

XI. Sanctions

The Phase II Regulations adopt the Proposed Rule. Thus, the Phase II Regulations provide for two primary sanctions (1) non-payment of improper DHS claims (and a duty to refund amounts collected in connection with such claims) and (2) \$15,000 civil monetary penalties for knowing violations. The agency considers both sanctions to be a “strong deterrent” to provider misconduct.

According to CMS, however, “violations of the physician self-referral prohibition may also

¹⁶² 69 Fed. Reg. at 16142.

¹⁶³ 69 Fed. Reg. at 16142.

¹⁶⁴ 69 Fed. Reg. at 16142.

¹⁶⁵ 69 Fed. Reg. at 16142.

¹⁶⁶ 69 Fed. Reg. at 16142.

¹⁶⁷ 69 Fed. Reg. at 16143.

¹⁶⁸ 69 Fed. Reg. at 16143.

be pursued under the False Claims Act,¹⁶⁹ a position that is strongly held by the OIG and the U.S. Department of Justice (“DOJ”), as well. By linking this statement to the observation that the “physician self-referral prohibition is implicated in nearly every financial relationship between and among physicians and entities that furnish DHS,” the qui tam whistleblower bar may be emboldened to vigorously pursue alleged Stark Law violations based upon so-called “technical violations” that were previously thought to be at little risk of False Claims Act enforcement.

This incentive, coupled with perennial CMS resource issues, will likely continue the trend of Stark Law enforcement through privately filed qui tam actions rather than through affirmative action by CMS. Assuming that DOJ and the OIG also exercise prosecutorial discretion regarding which Stark Law violation claims they will pursue — and only time will tell whether this assumption is well-founded — then, on balance, this may be a better alternative than the strict liability approach the statute authorizes CMS to use in non-payment and recoupment actions.

¹⁶⁹ 69 Fed. Reg. at 16125.

APPENDIX A

STARK LAW EXCEPTIONS

Ownership Interest Exceptions	Statutory Cite (42 U.S.C.)	Regulatory Cite (42 C.F.R.)
Publicly Traded Securities	§ 1395nn(c)	§ 411.356(a)
Mutual Funds	§ 1395nn(c)	§ 411.356(b)
Specific Providers	§ 1395nn(d)	§ 411.356(c)
Compensation Arrangement Exceptions	Statutory Cite (42 U.S.C.)	Regulatory Cite (42 C.F.R.)
Space Rental	§ 1395nn(e)(1)(A)	§ 411.357(a)
Equipment Rental	§ 1395nn(e)(1)(B)	§ 411.357(b)
Employment	§ 1395nn(e)(2)	§ 411.357(c)
Personal Services	§ 1395nn(e)(3)	§ 411.357(d)
Physician Recruitment	§ 1395nn(e)(5)	§ 411.357(e)
Isolated Transactions	§ 1395nn(e)(6)	§ 411.357(f)
Arrangements With Hospitals	§ 1395nn(e)(4)	§ 411.357(g)
Group Practice Arrangements With Hospitals	§ 1395nn(e)(7)	§ 411.357(h)
Payments By A Physician	§ 1395nn(e)(8)	§ 411.357(i)
Compensation Under \$300 Per Year (<u>Phase I</u>)	None	§ 411.357(k)
Fair Market Value Compensation (<u>Phase I</u>)	None	§ 411.357(l)
Medical Staff Benefits (<u>Phase I</u>)	None	§ 411.357(m)
Risk-Sharing Arrangements (<u>Phase I</u>)	None	§ 411.357(n)
Compliance Training (<u>Phase I</u>)	None	§ 411.357(o)
Indirect Compensation Arrangements (<u>Phase I</u>)	None	§ 411.357(p)
Charitable Donations by Physician (<u>Phase II</u>)	None	§ 411.357(j)*

Referral Services (<u>Phase II</u>)	None	§ 411.357(q)*
Obstetrical Malpractice Insurance (<u>Phase II</u>)	None	§ 411.357(r)*
Professional Courtesy (<u>Phase II</u>)	None	§ 411.357(s)*
Retention Payments in Underserved Areas (<u>Phase II</u>)	None	§ 411.357(t)*
Community-Wide Health Information Systems (<u>Phase II</u>)	None	§ 411.357(u)*
All Purpose Exceptions	Statutory Cite (42 U.S.C.)	Regulatory Cite (42 C.F.R.)
Physician Services	§ 1395nn(b)(1)	§ 411.355(a)
In-Office Ancillary Services	§ 1395nn(b)(2)	§ 411.355(b)
Pre-Paid Health Plan Services	§ 1395nn(b)(3)	§ 411.355(c)
Academic Medical Center Services (<u>Phase I</u>)	None	§ 411.355(e)
Implants (ASC) (<u>Phase I</u>)	None	§ 411.355(f)
Dialysis-Related Drugs (ESRD) (<u>Phase I</u>)	None	§ 411.355(g)
Preventive Screening Tests & Immunizations (<u>Phase I</u>)	None	§ 411.355(h)
Post-Cataract Surgery Eyeglasses & Contact Lenses (<u>Phase I</u>)	None	§ 411.355(i)
Intra-Family Rural Referrals (<u>Phase II</u>)	None	§ 411.355(j)*