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SPECIAL EDITION

STARK II PHASE III – “THE FULL PICTURE”

Highlights of the Phase III final rule, potential future changes, and the overall regulatory scheme



Andrew B. Wachler,
Esq.
Wachler & Associates,
PC
Royal Oak, MI



Adrienne Dresevic,
Esq.
Wachler & Associates,
PC
Royal Oak, MI

Introduction

On September 5, 2007, the Centers for Medicare and Medicaid Services (“CMS”) completed the long-awaited third and final installment in its rulemaking process under the federal physician self-referral prohibition commonly known as the “Stark law.”¹ The new final rule,² referred to as “Phase III,” responds to public comments regarding the Phase II interim final rule with comment period published on March 26, 2004,³ and addresses the entire Stark law regulatory scheme. As in Phases I and II, CMS has

continued its efforts in Phase III to reduce the regulatory burden on the healthcare industry through its interpretation and modification of previously promulgated exceptions to the Stark law’s general prohibition on referrals. The new regulations will be effective December 4, 2007.

Although Phase III is intended as the final phase of the CMS rulemaking process, it is actually not the last piece of the “Stark puzzle.” There are several other significant rulemaking proposals, pending legislation, and a CMS mandate regarding disclosures of hospital-physician financial relationships, any and all of which may lead to more changes to the Stark regulations and may have a profound impact on the healthcare industry. This article is intended nevertheless to set forth the “full picture” of the Stark law and regulations as of the conclusion of the Phase III rulemaking, and to provide health industry counsel with a tool to assist in navigating through the Stark regulations. This article will: (1) address the highlights of Phase III; (2) identify potential future changes to the Stark regulations; and (3) set forth the complete Stark regulatory scheme as finalized by Phase III.



The Editorial Board of *The Health Lawyer* is pleased to offer this Special Edition to the membership of the ABA Health Law Section. This is an additional benefit provided to Section members at no additional charge. Contributing writers for this edition are Andrew B. Wachler and Adrienne Dresevic, both partners in

the law firm of Wachler & Associates, P.C. Drew is a long-time and active member of the Editorial Board, and the author of prior articles in this publication and elsewhere on Stark and related regulatory issues. The authors, the Editorial Board, our Editor, Marla Durben Hirsch, and the staff of the ABA Health Law Section exerted considerable effort to put this material in your hands at the earliest possible time. We hope you will find it useful.

Charles M. Key
The Bogatin Law Firm, PLC



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mclark@hbctrial.com
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shelley.hubner@sdma.com

Alexandra Hien McCombs
Pinnacle Partners in Medicine
Dallas, TX
972/663-8552
amccombs@pinnaclepartnersmed.com

Daniel A. Cody
Reed Smith LLP
San Francisco, CA
T: 415/659-5909
dcody@reedsmith.com

David H. Johnson
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kathleen.scullyhayes@cms.hhs.gov

Young Lawyer Division

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The Health Lawyer Editor

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mdhirsch@comcast.net

Section Director

Jill C. Peña
American Bar Association
321 N. Clark Street
Chicago, IL 60610-4714
T: 312/988-5548 F: 312/988-9764
jillpena@staff.abanet.org

Stark II Phase I, II, and III – A Brief History

The original Stark self-referral prohibition was enacted in 1989 with the purpose of prohibiting physicians from referring patients for laboratory services to entities in which they had a financial interest. The self-referral ban, referred to as “Stark I” after Representative Pete Stark (D-CA), who introduced the legislation, went into effect on January 1, 1992. In 1993, the Stark ban was expanded to include additional health-care services considered to be particularly susceptible to overutilization as a result of physician financial interests, and to apply in part to Medicaid beneficiaries. The 1993 amendments, now referred to as “Stark II,” went into effect on January 1, 1995.

Stark II prohibits physician referrals of Medicare beneficiaries to entities with which they, or members of their immediate family, have a financial relationship for certain services itemized in the statute, referred to as “designated health services” or “DHS.” DHS include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including MRI, CT scans, ultrasound services, and nuclear medicine); radiation therapy services and supplies; durable medical equipment (“DME”) and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospitalization services. The Stark II ban also prohibits entities from making a claim for payment for the provision of DHS furnished pursuant to a prohibited referral.⁴

Stark I final regulations were not published until August 1995,⁵ several months after Stark II had gone into effect. While the Stark I final rule technically applied only to referrals for clinical laboratory services, as agency interpretation of a closely analogous prior law, it was assumed to apply in large part to other DHS as well. In January 1998,

the Stark II proposed regulations were issued.⁶ Although many elements of the Stark I final rule were included in the proposed rule, the Stark II proposed rule contained significant proposed changes.

On January 4, 2001, HCFA issued the first phase of its Stark II final regulations, referred to as “Stark II, Phase I.”⁷ Phase I of the rulemaking did not address all of the Stark law, and it was intended that a second phase of the rulemaking would be published to address the rest. Phase I addressed the general prohibition, general exceptions applicable to both ownership or investment interests and compensation arrangements, new exceptions that are applicable only to compensation arrangements, and definitions. Phase I only applied to referrals of Medicare beneficiaries. With two exceptions (Section 424.22(d), relating to home health services and Section 411.354(d)(1) relating to the definition of “set in advance”), the Phase I final regulations went into effect on January 4, 2002, one year after publication. The delayed effective date was selected in order to give individuals and entities time to restructure business arrangements in light of the Phase I requirements. For a comprehensive analysis of Stark II, Phase I, see “*Stark II Final Rule-Phase I A Kinder and Gentler Stark?*”, *The Health Lawyer, Special Edition, January 2001*.

On March 26, 2004, CMS issued Phase II of the final regulations. Phase II addressed provisions of the Stark law not addressed in Phase I and provided additional regulatory definitions, new regulatory exceptions, and responses to public comments on Phase I regulations.⁸ Phase I and Phase II of the final regulations were intended to be integrated and read together as a whole. Modifications and revisions to Phase I were indicated in the Phase II preamble and corresponding regulations. The Phase I and the Phase II rules, together, superseded the 1995 final rule,⁹ which had been applicable only to clinical laboratory services. For a comprehensive analysis of Stark II Phase II, see “*Stark II – Phase II – The Final Voyage*”, *The Health Lawyer, Special Edition, April 2004*.

On September 5, 2007, CMS issued Phase III of the final regulations.¹⁰ Phase III responds to comments on Phase II and, thus, addresses the entire Stark regulatory scheme. Phases I, II, and III of the rulemaking are intended to be read as a unified whole. CMS states that except as otherwise noted, to the extent that the preamble in Phase III uses different language to describe a concept that was addressed in Phase I or Phase II, the intent is to expound on previous discussions, not to change the scope or meaning.¹¹ For ease of reference, CMS republished the entire Stark regulatory text as a part of the Phase III final rule, but omitting 42 C.F.R. §§ 411.370-411.389 relating to advisory opinions. The regulatory text also includes 42 C.F.R.¹² §§ 411.357(v) and (w) (2006), relating to exceptions for arrangements involving donations of electronic prescribing and electronic health records technology. These two exceptions were published and finalized in separate 2005 and 2006 rulemakings.¹³

Summary of Stark II, Phase III Final Rule

This section will summarize the major points contained in the Phase III final rule. For the CMS summary set forth in the preamble of the Phase III final rule, see 72 Fed. Reg. 51070-51072 (2007). Further detail on some of the significant aspects of Phase III will also be set forth later in this article under the heading “Stark II – the Complete Final Regulatory Scheme.” Highlights of Phase III are as follows:

- **Safe harbor for fair market value is eliminated.** As part of Phase II, CMS created a voluntary “safe harbor” provision within the definition of “fair market value” applicable to hourly payments to physicians for their personal services. Due to numerous commenters’ concerns that the “safe harbor” was impractical and infeasible, Phase III eliminates it. CMS emphasized, however, that it will continue to scrutinize the fair market value of arrangements. Parties to a

transaction may calculate fair market value using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits within the definition of fair market value for purposes of Stark.¹⁴

- **A physician in the group practice must have a direct relationship with the group and provide services in the group's facilities.** CMS has modified the definition of "physician in the group practice" to make clear that an independent contractor physician must furnish patient care services for the group practice under a **direct** contractual arrangement with the group, and not between the group practice and other entity, such as a staffing entity. CMS also reiterated its position that an independent contractor physician is only considered a "physician in the group practice" when he or she is performing services in the group's facilities, and thus has a true nexus with the group's medical practice. Last, CMS made clear that the definition of "physician in the group practice" clearly encompasses only members (owners or employees) and independent contractors, and not other types of employment arrangements, such as staffing arrangements.¹⁵
- **Definition of referral – CMS clarifies the few, if any, situations in which a physician would personally furnish DME.** In Phase I, CMS stated that the definition of "referral" excludes services personally performed by the referring physician.¹⁶ In response to several commenters requesting clarification of whether certain types of services can be personally performed by the referring physician eliminating the need to meet a Stark exception, CMS noted that there are few, if any, situations in which a referring physician could personally furnish DME, because doing so would require the physician to be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier. CMS believes that it is highly unlikely that a referring physician would meet the criteria for personally performed

services when dispensing DME, including continuous positive airway pressure equipment ("CPAP"). CMS also notes that CPAP is DME that does not qualify for the in-office ancillary services exception.¹⁷

- **CMS makes changes to the group practice definition making clear that productivity bonuses can be based directly on "incident to" services but upon further reflection, CMS now states that overall profit shares cannot relate directly to "incident to" services.** Due to confusion expressed by many commenters, in Phase III, CMS revised the definition of "group practice" to make clear that productivity bonuses can be based directly on "incident to" services that are incidental to the physician's personally performed services, even if those "incident to" services are otherwise DHS referrals. For example, a physician can be paid a productivity bonus based directly on physical therapy services provided "incident to" his or her services. However, the productivity bonus cannot be directly related to any other DHS referrals, such as diagnostic tests. Further, although in Phase II CMS stated that overall profit shares could relate directly to "incident to" services, upon further reflection, CMS now states that its previous interpretation is inconsistent with the statutory language, which includes "incident to" services only in the context of productivity bonuses. Accordingly, under Phase III, profits must be allocated in a manner that does not directly relate to DHS referrals, including any DHS billed as an "incident to" service.¹⁸
- **Physicians "stand in the shoes" of their group practices.** Phase III includes new provisions addressing compensation arrangements in which a group practice (or other "physician organization" as newly defined in Phase III) is directly linked to the physician in a chain of financial relationships between the referring physician and a DHS entity. For purposes of determining whether a physician has a direct or

indirect financial relationship with a DHS entity to which the physician refers, under Phase III, the physician will "stand in the shoes" of his or her physician organization. CMS is mindful of many existing arrangements which have been properly structured to comply with the indirect compensation arrangements exception and is excepting existing indirect compensation arrangements that were entered into prior to the publication date of Phase III and that met the indirect compensation arrangements exception at the time of the Phase III publication date from this new so called "stand in the shoes" doctrine. Such exempted arrangements may continue to use the indirect compensation arrangement exception during the original or current renewal term of the agreement.¹⁹

- **Physicians can have a security interest in equipment that was sold to a hospital.** CMS has revised the regulatory text defining what constitutes an ownership interest for purposes of Stark's application to exclude a security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital. In the past, this security interest would have created an ownership interest in part of a hospital, and thus would have been considered a prohibited financial relationship. Under Phase III, this security interest will be considered a compensation arrangement between the physician and the hospital.²⁰
- **In-office ancillary shared services arrangements must be carefully structured and operated to satisfy the in-office ancillary services exception.** In response to commenters who wanted further guidance on physicians who provide DHS to their patients in a shared space in the same building, in Phase III, CMS states that physicians sharing a DHS facility in the same building must control the facility and the staffing at the time the DHS is furnished to the patient. As a practical matter, CMS points out that this

necessitates a block lease for the space and equipment used to provide the DHS. CMS also notes that common per-use or per-click fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute. Further, CMS opines that part-time, shared, off-site facilities (such as “condo” pathology laboratories) are readily subject to abuse. CMS will be addressing this potential for abuse in a separate rulemaking. In the meantime, however, CMS cautions parties involved in shared arrangements in the same building and in off-site buildings that the arrangements must fully comply with the in-office ancillary services exception in operation, not just on paper.²¹

- **Academic medical centers exception clarified.** Phase III revises language in the academic medical exception to clarify that the total compensation from each academic medical center component to a faculty physician must be set in advance and not determined in a manner that takes into account the volume or value of the physician’s referrals or other business generated by the referring physician within the academic medical center. Additionally, language was added to the exception to provide that for purposes of determining whether the majority of physicians on the medical staff of a hospital affiliated with an academic medical center consists of faculty members, the affiliated hospital must include or exclude all individuals holding the same class of privileges at the affiliated hospital.²²
- **Intra-family rural referrals exception modified to include an alternative distance test.** In Phase II of the rulemaking, CMS created a new exception for certain referrals from a referring physician to his or her immediate family member or to a DHS entity with which the physician’s immediate family member has a financial relationship. In part, the exception requires that the patient reside in a

rural area and that there is no other person or entity available to furnish the referred DHS in a timely manner, at the patient’s residence, or within 25 miles of the patient’s residence. Phase III modifies the exception to include an alternative distance test based on transportation time (45 minutes) from the patient’s residence. This new alternative test requires a case-by-case analysis of the conditions that exist at the time of the referral (for example, in the winter there may be snow blocking access to roads). CMS recommends that physicians choosing to rely upon this 45-minute alternative transportation test should maintain documentation (e.g., Mapquest and published weather reports) of the information used for determining transportation time.²³

- **Holdovers now permitted in personal service arrangements.** Phase III modifies the personal service arrangements exception to include a provision which permits a holdover personal service arrangement (services provided after the term of the contract expires) for up to six months for personal service arrangements that otherwise met the requirements of the personal services exception. This new holdover concept is similar to the holdover provisions permitted in the exceptions for office space and equipment leases.²⁴
- **Physician recruitment exception relaxed.** The most drastic changes to the Stark regulations contained in Phase III are changes to the physician recruitment exception. Phase III makes a number of changes that relax the exception. The physician recruitment exception is designed to protect certain remuneration that is provided by a hospital to a physician as an inducement for the physician to relocate his or her medical practice into the “geographic area served by the hospital.” Several changes were made to the exception as follows:
 - Modifying the exception to allow group practices to impose practice restrictions if they do not “unreason-

ably restrict” the recruited physician’s ability to practice in the “geographic area served by the hospital.”

- Adding a special option rule for rural hospitals in which the “geographic area served by the hospital” may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the “geographic area served by the hospital” may include noncontiguous zip codes.
- Adding a provision allowing groups in a rural area or a health professional shortage area (“HPSA”) that recruit a physician to replace a retired, deceased, or relocated physician to either allocate the costs attributed by the recruited physician based upon (1) the actual additional incremental costs or (2) the lower of a per capita allocation or 20 percent of the practice’s aggregate costs.
- Adding a provision that allows rural hospitals to recruit physicians into an area outside of the “geographic area served by the hospital” if the Secretary of the Department of Health and Human Services (“DHHS”) determines in an advisory opinion that the area has a demonstrated need for the physician.
- Amending the recruitment exception to now apply to rural health clinics in the same manner as it applies to hospitals and federally qualified health centers.
- Adding provisions exempting certain physicians from the relocation requirement. Recruited physicians will be exempt from the relocation requirement if they were employed full time by a federal or state bureau of prisons (or similar agency), the Departments of Defense or Veterans Affairs, or facilities of the Indian Health Service. The new exemption only applies if the physician did not

maintain a separate private practice in addition to the full-time employment. Physicians may also be exempt from the relocation requirement if the Secretary of DHHS deems in an advisory opinion that the physician has not established a medical practice.

In addition to the above modifications and amendments, CMS also clarified that the provisions of the recruitment exception that apply to recruitment arrangements involving physicians who join an existing practice do not apply when the recruited physician is just co-locating or sharing space with an existing practice and does not join the practice.²⁵

- **Inadvertent excess nonmonetary compensation can now be cured.** In Phase I of the rulemaking, CMS established an exception to protect non-monetary compensation provided to physicians up to \$300 (adjusted annually for inflation). Phase III makes two substantive changes to the exception by: (1) allowing physicians to repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception; and (2) allowing entities without regard to the \$300 dollar limit to provide one medical staff appreciation function (such as a party) for the entire medical staff per year. In order to take advantage of the excess nonmonetary repay provision, the value of the excess compensation cannot be more than 50 percent of the annual limit and the physician must return the excess amount by the end of the calendar year in which it was received or within 180 days after received, whichever is earlier. Further, this new provision only applies to situations in which the entity inadvertently provides excess nonmonetary compensation to the physician.²⁶
- **Fair market value exception expanded to cover compensation from a physician.** Phase III amends the exception for fair market value to permit application of the exception to arrangements involving fair market value compensa-

tion to physicians from DHS entities, as well as to arrangements involving fair market value compensation to DHS entities from physicians. CMS notes that the expansion of the fair market value exception will require parties to use the fair market value exception rather than the payments by a physician exception (which cannot be used if another exception applies and which CMS believes is less transparent) for payments by physicians when payments by a physician to a hospital are, for example, for equipment leases of less than one year. CMS also notes that the fair market value exception is not applicable to arrangements for the rental of office space. Such office space arrangements must be structured to meet the rental of office space exception.²⁷

- **Compliance training exception expanded.** Phase III amends the compliance training exception to cover compliance training programs that involve continuing medical education (“CME”) credit so long as the compliance training is the primary purpose. CMS states that the revised exception does not protect traditional CME content under the guise of compliance training.²⁸
- **Professional courtesy exception revised to delete notification requirement.** Phase III modifies the professional courtesy exception by deleting the requirement that an entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation. Notwithstanding the deletion, CMS does state that it believes it is a prudent practice to provide such notification, and, in fact, insurers may require such notification. Phase III also modifies the exception to clarify that it applies only to hospitals and other providers with formal medical staffs (but would include group practices), and not to suppliers, such as laboratories or DME companies.²⁹
- **Retention payments in underserved areas exception modified in several**

respects. Phase III modifies the exception for retention payments in underserved areas in several respects, including expanding the exception by permitting certain retention payments in the absence of a written recruitment offer, by adding flexibility for retention payments to physicians who serve underserved areas and populations, and by allowing rural health care clinics to make retention payments. Among other changes, Phase III makes the following changes to the exception:

- Phase III revises the exception to permit a hospital, rural health clinic, or federally qualified health center to offer assistance to a physician who does not have a bona fide written offer of recruitment or employment if the physician certifies in writing that he or she has a bona fide opportunity for future employment which would require relocation of his or her medical practice at least 25 miles to a location outside of the geographic area served by the hospital, rural health clinic, or federally qualified health center. In circumstances in which the physician provides written certification instead of a bona fide written offer, the retention payment may not exceed the lower of: (1) an amount equal to 25 percent of the physician’s annual income; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician.
- Phase III further expands the exception to permit retention payments that otherwise satisfy the requirements of the exception when: (1) the physician’s current medical practice is located in a rural area, a HPSA, or an area or demonstrated need determined by the Secretary of DHHS in an advisory opinion; or (2) at least 75 percent of the physician’s patients either reside in medically underserved area or are members of a medically underserved population. The location of the hospital in a HPSA is no longer a requirement under the exception.³⁰

Other Recent Proposed Stark Developments on the Horizon

Medicare 2008 Proposed Physician Fee Schedule – Common Healthcare Arrangements Under Attack

The September 5, 2007 Phase III final rule comes out amid a flurry of other current activity that could have a significant impact on Stark. Throughout the preamble of the Phase III rulemaking, CMS identifies certain issues for further study and potential change in a separate rulemaking process. CMS proposed several amendments to the Stark regulations in the 2008 Medicare Proposed Physician Fee Schedule (“MPPFS”), issued in July 2007.³¹ These MPPFS proposals are separate from, and in addition to, the revisions in the Phase III final rule. These proposals are noteworthy in that they contain discussions by CMS of its concern regarding many common healthcare structures. If adopted, the MPPFS proposals could be effective as early as January 1, 2008.

The “Physician Self-Referral Provisions” section of the MPPFS covers changes to the reassignment rules and anti-markup rule relating to diagnostic tests, burden of proof, the in-office ancillary services exception, obstetrical malpractice insurance subsidies, per-click payments in space and equipment leases, non-compliant relationships, percentage compensation arrangements, stand-in-the-shoes doctrine, alternative criteria for satisfying certain exceptions and services furnished “under arrangements.” The MPPFS also covers proposals related to independent diagnostic testing facilities (“IDTF”), which may have a significant impact on many common “in-office” ancillary service arrangements with physician practices. A few of the important features of the MPPFS proposals are briefly summarized below. For specific detail regarding the MPPFS proposals, see 72 Fed. Reg. 38179-38187 (2007).

- **No Marking Up Purchased or Reassigned Technical and Professional Services.** CMS has long expressed its

concerns regarding certain healthcare structures such as pathology pod labs involving the shared use of equipment, technologists, and pathologists between physician practices and pathology labs. CMS also believes that certain diagnostic testing arrangements between physician practices and diagnostic testing suppliers raise potential fraud and abuse concerns. In order to address its concerns, CMS proposed prohibiting physicians and practices from marking up the outside supplier’s net charge for the diagnostic test to the Medicare program. Notably, this anti-markup prohibition applies regardless of whether the diagnostic test is purchased outright from the supplier or whether the practice is billing Medicare pursuant to a reassignment from the supplier. The proposed rule applies to both the professional component and the technical component of the services. The only exception to this anti-markup rule is for full-time employees.³²

If finalized, this proposal will remove virtually all economic incentives for physician practices to bill Medicare for the professional component of diagnostic tests not performed by full-time employees of the practice (which is commonly done through the use of the Stark physician services exception). Under the proposal, the practice will not be able to recover from Medicare the overhead practice expense of interpretations performed in the practices facilities by part-time or independent contractor physicians. Consequently, for example, practices that currently utilize part-time or independent contractor radiologists for the interpretation of diagnostic imaging services may decide to discontinue billing Medicare for such interpretation services or employ, if feasible, a radiologist on a full-time basis.

- **Narrowing of the Stark In-Office Ancillary Services Exception.** The in-office ancillary services exception is arguably the single most important exception to the Stark law, which allows physicians to furnish ancillary

services (e.g., x-ray, lab, ultrasound, physical therapy) in their practices. In the proposed MPPFS, CMS expressed its concern that this exception is being inappropriately used for services that are not closely connected to the physician’s practice. Despite its concerns, CMS declined to issue a specific proposal, but is soliciting comments as to whether the exception should be narrowed or limited to some extent.³³

- **Limitations on Per-Click Leases for Space and Equipment.** Presently per-click lease payments are generally permitted under the Stark law if the per-click payment is fair market value. In the proposal, CMS is now reconsidering its position stating that it considers certain per-click payment arrangements to be susceptible to abuse. Thus, CMS has proposed to prohibit the use of per click-lease payments involving space and/or equipment leases in those situations where an entity owned by a physician leases space and/or equipment to another entity and the physician subsequently refers patients to that other entity for services. For example, the proposal would prohibit a cardiologist from leasing a CT scanner to the hospital on a per-click basis if that cardiologist will be referring patients to the hospital for cardiovascular CT angiography services. CMS is also considering whether it should prohibit per-click payments by a physician to an entity from which the physician leases space or equipment if that entity refers patients to the leasing physician.³⁴

- **Prohibition on Percentage Leases with Referrals Sources.** Many of the current Stark regulatory exceptions allow percentage compensation arrangements, such as the space and equipment lease exceptions, the personal service exception and the fair market value exception. CMS is now proposing that percentage based compensation can only be used when paying for personally performed physician services and that the percentage must be based on the revenues directly

resulting from the physician services. If finalized, this proposal would prohibit many common compensation arrangements involving the use of percentage based rental and management fees.³⁵

- **“Under Arrangements” Under Attack.** Pursuant to the current Stark regulations, an entity is not considered to be an entity “furnishing” DHS (a “DHS entity”), for purposes of the general prohibition, unless it is the entity that is paid by Medicare for the DHS.³⁶ The current definition of DHS entity permits certain joint venture arrangements between hospitals and referring physicians in which the physicians are providing services to the hospital “under arrangements.” In the MPPFS, CMS expressed its concerns with “under arrangements” ventures between hospitals and physicians that appear to be designed to enable the physician-investors to profit from referrals to the hospital.

In addition, CMS agreed with the Medicare Payment Advisory Commission’s (“MedPac”) March 2005 report to Congress that physician ownership of entities that provide services and equipment to imaging centers and other healthcare providers creates inappropriate financial incentives. MedPac recommend that CMS expand the definition of physician ownership to include interest in an entity that derives a substantial portion of its revenue from a provider of DHS. Although CMS concurs with MedPac’s concerns, it did not adopt the MedPac approach; instead, the CMS proposal provides that the DHS entity is either the entity that submits a claim to Medicare for the DHS, or the entity that performed the DHS. If CMS’ proposal were finalized, it would essentially bar referring physicians from participating in joint ventures that provide DHS services “under arrangements” to hospitals or other providers. Given that hospital-physician “under arrangements” joint ventures are commonplace, this proposal would require the restructuring of a significant

number of arrangements that comply with current law.³⁷

- **Stand in the Shoes.** In the MPPFS, CMS proposed to collapse the indirect financial relationship concept when a DHS entity owns or controls another entity with which a physician has a financial arrangement. Under the doctrine, the physician would be deemed to have the same financial relationship with the DHS entity as he or she has with the controlled or owned DHS entity.³⁸
- **Ownership or Investment in Retirement Plans.** Current Stark regulations provide that a physician does not have an ownership or investment interest in an entity that furnishes DHS solely by having an interest in that entity’s retirement plan. CMS learned that physicians are attempting to abuse this exception by using their retirement plans to purchase entities that provide DHS and to which the physician refers patients. For example, a group of physicians participates in a retirement plan and that plan invests its funds by purchasing an MRI center. The physicians will then refer their patients to the MRI center without violating Stark because they claim they have an investment in the retirement plan, not the MRI center. In an attempt to close this loophole, in the MPPFS, CMS proposed to apply the ownership or investment exception only to investment interests in legitimate employer-sponsored retirement plans.³⁹
- **Independent Diagnostic Testing Facility (“IDTF”) Issues.** In a related matter, the MPPFS also provided some significant proposed revisions, additions, and clarifications to the existing IDTF performance standards. Of significant importance is CMS’ controversial standard that would significantly impact block leasing and other shared imaging arrangements involving IDTFs. This new standard would prohibit a fixed site IDTF from sharing space, equipment, or staff, or from subleasing its operations to

another individual or organization. If this proposal were adopted, it would eliminate the ability of an IDTF to enter into any type of sublease arrangement with a physician practice, hospital, or other individual or entity. IDTFs already involved in sharing arrangements would need to have them reviewed and restructured.⁴⁰

- **Other Miscellaneous Issues.** Other sections relating to Stark issues contained in the MPPFS include: period of disallowance for noncompliant financial relationships; obstetrical malpractice insurance subsidies; burden of proof; and alternative criteria for satisfying certain exceptions.⁴¹

The recent MPPFS proposals reflect CMS’ intent to close what it perceives as current regulatory loopholes by essentially prohibiting or restricting many common and currently legal health care arrangements. If finalized, these proposals will require the restructuring or unwinding of many existing arrangements.

The Stark Whole Hospital Exception Under Attack

In addition to the MPPFS proposals, on August 1, 2007 the U.S. House of Representatives passed a bill which would have a significant impact on the permissible legal structures of physician-owned hospitals.⁴² The bill is contained in the Children’s Health and Medicare Protection Act of 2007 which would expand the State Children’s Health Program (“SCHIP”). The House-passed bill would amend the Stark whole hospital exception as follows:

- Eliminate the whole hospital exception so that physicians cannot self-refer to hospitals (not just specialty hospitals);
- Grandfather hospitals that were in operation with Medicare provider agreements as of July 24, 2007;
- Require grandfathered hospitals to meet certain standards within 18 months, as follows:

- Prevent growth (e.g., no new rooms or beds);
- Require disclosure of ownership;
- Limit physician ownership to an aggregate of 40% and no more than 2% individually;
- Disclose to patients if the hospital fails to have 24-hour physician coverage.

At the time of publication, the proposed amendments to the whole hospital exception face uncertainty because they are not included in the Senate version of the SCHIP bill and the President is threatening to veto the legislation.⁴³

Mandated Disclosure of Investment and Compensation Relationships

CMS has also recently announced its intention to mandate Medicare-participating hospitals to report to CMS details of their financial relationships with their referring physicians. This mandate emanates from Section 506 of the Deficit Reduction Act (“DRA”), enacted on February 8, 2006, which directed the Secretary of DHHS to develop a plan to address certain issues relating to physician investment in specialty hospitals. In August 2006, DHHS stated it would require all hospitals to provide information to CMS on a periodic basis concerning their investment and compensation relationships with physicians pursuant to the Stark regulations at 42 C.F.R. § 411.361.⁴⁴

Commencing September 2007, CMS has initially selected 500 hospitals that will be required to report financial information. CMS can request, among other information, the name and unique physician identification number (“UPIN”) or national provider identifier (“NPI”) of each physician (and any immediate family member) with a reportable financial relationship, the covered services furnished by the entity, and the nature of the financial relationship.⁴⁵ Reportable financial relationships include any ownership or investment interest, as defined at Section 411.354 (b) (2006), or

any compensation arrangements, as defined at Section 411.354 (c) (2006), excluding ownership or investment interests in publicly traded securities and mutual funds.⁴⁶ Hospitals that fail to timely report are subject to civil monetary penalties of up to \$10,000 for each day beyond the deadline.⁴⁷

Stark II – The Complete Final Regulatory Scheme

The remainder of this article will set forth the complete Stark II final regulatory scheme as finalized by Phase III. The Stark regulatory text has been republished in its entirety (except for provisions related to advisory opinions) in the Phase III rulemaking.⁴⁸ The Stark regulatory scheme consists of: (1) the scope (411.350); (2) definitions (411.351); (3) the group practice definition and special rules for compensation (411.352); (4) the general prohibition and limitation on billing (411.353); (5) financial relationships – direct and indirect ownership and compensation arrangements (411.354); (6) exceptions applicable to both ownership/investment and compensation arrangements (411.355); (7) exceptions applicable only to ownership or investment interests (411.356); (8) exceptions applicable only to compensation arrangements (411.357); and (9) reporting requirements (411.361).

As a starting point, the Stark law prohibits a physician from making a *referral* for certain *designated health services* (DHS) payable by Medicare to an entity with which the physician (or an *immediate family member*) has a *financial relationship* (ownership or compensation), unless an exception applies. The Stark law also prohibits the entity from filing claims with Medicare (or billing another individual, entity or third party payer) for those referred services. The Stark law establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of abuse. Penalties for violating Stark are severe and include denial of payment, refund

of payment, and imposition of civil monetary penalties.⁴⁹

Scope of Regulations – Section 411.350

The Stark regulations do not supercede Medicare payment and billing rules and policies. They do, however, affect the application of these Medicare rules and policies. The Stark regulations now make clear that nothing in the Stark rules alters a party’s obligation to comply with: (1) the reassignment rules; (2) the rules regarding purchased diagnostic tests; (3) the rules regarding payment for “incident to” services and supplies; or (4) any other applicable Medicare law, rule, or regulation.⁵⁰

This recent amendment to the scope of the Stark regulations comes at a time of apparent confusion in the healthcare community regarding the interplay between Stark and other Medicare rules and regulations. For example, following the recent amendment to the Medicare reassignment rules, an independent contractor physician may reassign his right to bill Medicare to an entity, regardless of whether he or she was on or off the premises of that entity.⁵¹ But, if that independent contractor physician reassigns his or her right to payment, for example, to a group practice with which he or she has a financial relationship, the Stark regulations must also be satisfied, which require that the independent contractor physician perform the services on site in the group’s facilities.⁵²

Definitions – 411.351

The definition section of the Stark regulations contains numerous definitions, and unless the context indicates otherwise, the meanings set forth in Section 411.351 apply. This section will highlight some of the significant definitions that trigger application of the Stark self-referral ban but it does not address all of the definitions. For a comprehensive listing, please see 42 C.F.R. § 411.351.

Physician. For purposes of Stark’s application, physician means a doctor of medicine or osteopathy, a doctor of

dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.⁵³

Immediate Family Member. The Stark self-referral prohibition states that if a physician or *immediate family member* has a financial relationship with an entity, the physician cannot refer a Medicare patient to that entity for DHS unless an exception applies. Section 411.351 sets forth the wide-ranging list of individuals that qualify as a physician's *immediate family member*. These individuals include: husband or wife; birth or adoptive parent, child, or sibling; stepparent; stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.⁵⁴

Referral. In order to trigger the Stark physician self-referral ban, there must be a physician *referral* of DHS. A *referral* is defined as a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation and any DHS ordered or performed by the consulting physician or under the supervision of the consulting physician, and the request or establishment of a plan of care by a physician that includes the furnishing of DHS. There are certain carved out exceptions from the definition of *referral* for pathologists, radiologists, and radiation oncologists pursuant to a consultation requested by another physician.⁵⁵ In Phase III, CMS rejected a commenter's request to expand the consultation exception to anesthesiologists, noting that the statutory exception is limited to pathologists, radiologists, and radiation oncologists who meet certain criteria.⁵⁶

Phase I of the rulemaking excluded from the definition of *referral* services personally performed by the referring physician. However, the definition includes services provided by a physician's employees, co-workers, or independent contractors.⁵⁷ After consideration of this

issue, in Phase II CMS adhered to its original determination that "incident to" services, as well as services performed by the physician's employees, are *referrals* within the meaning of the Stark law.⁵⁸ In Phase III, CMS stated that it is possible for a physician to order and personally furnish antigens to a patient and to order a refill for, and personally refill an implantable pump. In these circumstances, the services are personally performed so there is no *referral*, and no Stark exception would be needed. CMS did state, however, that there are few, if any, situations in which a referring physician could personally furnish DME, because doing so would require the physician to be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier.⁵⁹

DHS. The Stark II law lists eleven categories of DHS covered by the self-referral prohibition.⁶⁰ Phase I of the rulemaking defined certain categories of DHS by reference to CPT and HCPCS codes.⁶¹ These categories include: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy and speech pathology services; (4) radiology and certain other imaging services; and (5) radiation therapy services and supplies.⁶² The list of codes is updated on an annual basis in the physician fee schedule final rule.⁶³ CMS also maintains the list on its website at www.cms.hhs.gov. Additionally, Phase I defined the remaining DHS categories in regulatory descriptions, but not by codes. These categories include: (1) durable medical equipment; (2) parenteral and enteral nutrients, equipment, and supplies; (3) prosthetics, orthotics, and prosthetic devices; (4) home health services and supplies; (5) outpatient prescription drugs; and (6) inpatient and outpatient hospital services.⁶⁴

Although in the 2004 Phase II rule CMS declined to include nuclear medicine as DHS (as part of the categories "radiology imaging services" and "radiation therapy supplies"), nuclear medicine became DHS effective January 1, 2007.⁶⁵

Phase I defined outpatient prescription drugs as "all prescription drugs covered by Medicare Part B."⁶⁶ In Phase II, however, in light of the expanded coverage of outpatient prescription drugs pursuant to section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"),⁶⁷ CMS stated that it would revisit the definition of outpatient prescription drugs in a future rulemaking.⁶⁸ The definition of outpatient prescription drugs now includes all drugs covered by Medicare Part B or Part D.⁶⁹

Entity Furnishing DHS. In general, under the Phase II regulatory text, a person or entity was considered to be *furnishing* DHS if CMS made payment to that person or entity, either directly or upon assignment, or reassignment.⁷⁰ Phase III made no substantive changes to the definition of *entity*; however, the 2008 MPPFS contains a proposal that would change the definition of *entity*, as currently set forth in Section 411.351, to also cover the person or entity that either provides the DHS or "causes a claim to be presented" for DHS.⁷¹

If adopted, this proposal would force the restructuring of many existing joint venture arrangements between hospitals and referring physicians in which the physicians are providing services to the hospital "under arrangements." Additionally, in the Phase III preamble, CMS sets forth excerpts from MedPac's March 2005 report to Congress that provides that physician ownership of entities that supply services and equipment to imaging centers and other healthcare providers creates inappropriate financial incentives. MedPac recommends that CMS expand the definition of physician ownership to include interest in an entity that derives a substantial portion of its revenue from a provider of DHS. In Phase III, CMS notes that any changes to the definition of *entity* or otherwise to address these concerns will be made in a separate rulemaking. CMS notes that these relationships are still subject to the Stark rules on indirect compensation arrangements and appear

highly suspect under the anti-kickback statute.⁷²

Physician Organization. Phase III of the final rulemaking added a definition in Section 411.351 for *physician organization*. *Physician organization* means a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the group practice definition in Section 411.352. This new definition is used in defining direct compensation arrangements in Section 411.354 under the new “stand in the shoes” doctrine, which is set forth in further detail in the discussions regarding Section 411.354 below.

Miscellaneous Definitions. Phase III of the final rulemaking also added definitions in Section 411.351 for *downstream contractor* and *rural area*. Additionally, Phase III eliminated the fair market value safe harbor for physicians’ personal services that was formerly included in the definition of *fair market value*.⁷³

Group Practice Definition and Special Rules on Compensation – 411.352

Although the *group practice* definition contained in 42 C.F.R. § 411.352 is not an exception to the self-referral prohibition in and of itself, it has significant meaning to any group of physicians that want to take advantage of the in-office ancillary services and physician services exceptions. The Stark law also affords *group practices* more flexibility in compensating physicians (i.e., only *group practice* physicians may be compensated in a manner that takes into account services furnished “incident to” a physician’s personally performed services). Phase I of the final rulemaking addressed the requirements for qualification as a *group practice*.⁷⁴ Phase II made minor changes to the definition, such as establishing a new grace period for start-up groups, clarifying the single entity test and the two or more physicians test, and softening the unified business test.⁷⁵

In order to qualify as a group practice, the group must: (1) be a single legal entity; (2) have at least two members (employees or owners); (3) provide the full range of patient care services; (4) with certain exceptions, ensure that members provide at least 75% of their patient care services through the group; (5) have predetermined methods for distribution of expenses and income; (6) be a unified business; (7) not allow members to directly or indirectly receive compensation based on volume or value of referrals (except as provided in the special rules for compensation); and (8) have its members conduct no less than 75% of the physician-patient encounters.⁷⁶

The *group practice* definition also contains special rules for productivity bonuses and profit shares which are applicable to all physicians in a group practice (employees, owners, and independent contractors).⁷⁷ These special rules allow *group practices* to pay a physician in the group a share of overall profits of the group provided the share is not determined in any manner that directly relates to the volume or value of referrals of DHS by the physician. A *group practice* may also pay a physician in the *group practice* a productivity bonus based on services that the physician has personally performed or services “incident to” such personally performed services.⁷⁸ In Phase III, CMS revised the definition of group practice to make clear that productivity bonuses can be based directly on “incident to” services that are incidental to the physician’s personally performed services, even if those “incident to” services are otherwise DHS referrals. Further, CMS now says that profits must be allocated in a manner that does not directly relate to DHS referrals, including any DHS billed as an “incident to” service.⁷⁹

Prohibition of Certain Referrals and Limitations on Billing – 411.353

The basic prohibition on physician self-referral under the Stark law is set forth in Section 411.353 of the regulations. Because of the severe sanctions that can result from inadvertent viola-

tions of the self-referral prohibition, Section 411.353 contains an exception for certain arrangements that involve temporary non-compliance. The temporary non-compliance exception can only be used once every three years with respect to the same referring physician and is not applicable to certain exceptions (nonmonetary compensation and medical staff incidental benefits).⁸⁰

Section 411.353 also contains an exception, which allows payment to certain entities, despite a prohibited referral, if the entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the DHS to the entity.⁸¹

In Phase III, commenters requested clarification regarding how long a DHS entity would be precluded from submitting claims for DHS referred by a physician pursuant to a prohibited referral. CMS noted that the Stark law does not provide an explicit limitation on the billing and claims submission prohibition and that CMS would address the issue in another rulemaking. This is consistent with CMS commentary in the MPPFS in which CMS introduced a concept for a new “alternative method of compliance provision” which might address certain arrangements that fail to meet certain exceptions because of innocent technical violations. This new concept would complement the temporary non-compliance exception at Section 411.353(f), not replace it.⁸² In the MPPFS, CMS also solicited comments on how long a non-compliant financial relationship should taint physician referrals. Specifically, CMS solicited public comment on how to establish a “period of disallowance” during which referrals to an entity are considered tainted and the receiving entity cannot bill for the services furnished pursuant to such tainted referrals.⁸³

Financial Relationship, Compensation, and Ownership or Investment Interest – 411.354

Section 411.354 defines the universe of financial arrangements that

are subject to the Stark self-referral prohibition. The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is one of the factual predicates triggering application of Stark. Financial relationships are defined to include direct and indirect ownership and investment interests, and direct and indirect compensation arrangements between referring physicians and DHS entities.⁸⁴ In addition to defining financial arrangements, Section 411.354 also sets forth specific rules governing aspects of compensation arrangements such as the special rules for when compensation is “set in advance”, and whether time-based or unit-based compensation methodologies take into account the “volume or value” of referrals or “other business generated between the parties.”⁸⁵

Direct Relationships – “Stand in the Shoes” Doctrine

In Phase II of the rulemaking, the definition of referring physician was modified to clarify that a referring physician may be treated as “standing in the shoes” of his wholly owned professional corporation.⁸⁶ This clarification was made in response to commenters who noted that the fact that a physician practices through a wholly owned PC should not convert a direct financial relationship with a DHS entity into an indirect relationship.⁸⁷

Although in Phase II CMS made clear the modification did not apply in the group practice context, Phase III amends Section 411.354 (c) to add a “stand in the shoes” provision under which referring physicians will be treated as “standing in the shoes” of their group practices (and other *physician organizations*).⁸⁸ Under the regulations as finalized by Phase III, for purposes of determining whether a physician has a direct or indirect financial relationship with a DHS entity to which the physician refers, the physician will “stand in the shoes” of his or her *physician organization*. Parties must now analyze the arrangement between a

DHS entity and a group practice (e.g., lease of office space) under the various direct compensation arrangements exceptions, without using the indirect compensation arrangements definition or exception.⁸⁹ Certain arrangements which were properly structured to comply with the indirect compensation arrangements exception are exempt from the new “stand in the shoes doctrine” and may continue to use the indirect compensation arrangement exception during the original or current renewal term of the agreement. After that, the relationship will need to meet a direct exception.⁹⁰

Indirect Compensation Relationships

Phase I of the rulemaking established a three-part test that defines the universe of indirect compensation arrangements that may potentially trigger disallowance of claims and penalties. Phase I also created an exception for the subset of indirect compensation arrangements that will not trigger disallowances or penalties.⁹¹ If an arrangement meets the indirect compensation definitional three-part test, it must comply with the requirements of the indirect compensation arrangements exception at Section 411.357(p) if the physician refers DHS to the entity.

Ownership

As with compensation relationships, the definition of ownership or investment interests also includes indirect ownership or investment interests. Unlike indirect compensation relationships, however, there is no corresponding indirect ownership or investment exception. Instead, indirect ownership or investment interests must be structured to comply with an exception applicable to ownership (exceptions contained in 411.355 or 411.356). The definition of indirect ownership or investment interests does incorporate a knowledge element that should, in most circumstances, sufficiently limit the universe of prohibited interests so that many remote interests may not trigger the self-referral prohibition.⁹²

Under Phase III, a security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital will be considered a compensation arrangement between the physician and the hospital, not an ownership interest.⁹³

There is also a pending proposal in the MPPFS which could amend Section 411.354(b) with respect to the current carve-out from the definition of ownership or investment interest relating to retirement plans. If finalized, the proposal would limit the carve-out in the ownership definition only to investment interests in legitimate employer-sponsored retirement plans.⁹⁴

Special Rules on Compensation – “Set in Advance”

Section 411.354 (d) sets forth special rules that are applicable only to compensation such as the “set in advance” standard, and the “volume or value of referrals” and “other business generated between the parties” standards in connection with unit-based compensation.⁹⁵

There are many Stark exceptions (e.g., the personal services exception, and the fair market value exception) that require that compensation be “set in advance.” The “set in advance” standard requires that the compensation formula, but not the aggregate amount of compensation, be established at the inception of the arrangement. In the Phase I rulemaking, CMS interpreted the standard to prohibit most percentage compensation arrangements.⁹⁶ In Phase II, CMS reversed its earlier position deleting language that would exclude percentage based compensation formulas from meeting the “set in advance” standard.⁹⁷ Although Phase III does not modify the “set in advance” standard, CMS has proposed modifications to the standard in the MPPFS. The proposal would amend the standard to specifically limit the use of percentage based compensation arrangements to only those that directly result from personally performed physician services.⁹⁸

General Exceptions to the Referral Prohibition Applicable to Both Ownership/Investment and Compensation – 411.355

Section 411.355 sets forth various exceptions which are applicable to both ownership/investment financial relationships and compensation relationships. The exceptions listed in Section 411.355 include the: (a) physician services exception; (b) in-office ancillary services exception; (c) services furnished by an organization to enrollees exception; (d) reserved; (e) academic medical centers exception; (f) implants furnished in an Ambulatory Surgical Center (“ASC”) exception; (g) Erythropoietin (“EPO”) and other dialysis-related drugs exception; (h) preventative screening tests, immunizations, and vaccines exception; (i) eyeglasses and contact lenses following cataract surgery exception; and (j) intra-family rural referrals exception. This section of the article will focus on some of the more commonly used exceptions contained in Section 411.355. For specific details regarding each exception, see 42 C.F.R. § 411.355.

Physician Services Exception – 411.355(a)

The physician services exception enables group practices to make referrals within their group practices for physician services that are DHS (e.g., the professional component of radiology services, or professional pathology services) and that are performed or supervised by either a member (employee or owner) of the group practice or by a *physician in the group practice* (independent contractor). A *physician in the group practice* is only considered to be in the group when he or she is performing services in the group practice’s facilities. For purposes of this exception, professional DHS services that are performed by a member of the group practice may be provided on or off-site but professional services of an independent contractor physician must be performed in the group practice’s facilities. Therefore, the exception is not applicable to services provided by independent contractor physicians in off-site

locations that are not considered the group’s facilities. For example, a group of orthopedic physicians that contract with an independent radiologist to perform the interpretation and reporting of imaging services provided by the group would be precluded from relying upon the physician services exception if the independent contractor radiologist performed the professional services off-site at a remote location.⁹⁹

In Phase III, CMS notes that it continues to study the issue of independent contractor pathologists who perform services for group practices in off-site “pod labs” that are presumably able to meet the requirement of providing the services in the group practice’s facilities.¹⁰⁰ Of particular relevance to this issue, however, is the commentary and proposals set forth in the MPPFS which would prohibit a physician (or group) from marking up the professional component of services (including imaging and pathology services) unless the physician were a full-time employee.¹⁰¹ If this proposal were finalized, it would significantly diminish the importance of the “on-site” requirement of the physician services exception in that groups would not be permitted to mark-up charges for professional services provided by contractors (physicians *in the group*) under any circumstances, even if the services were provided on-site.

In-Office Ancillary Services Exception – 411.355(b)

The in-office ancillary services exception has arguably been the single most important exception in the Stark law. This exception prompted numerous comments in response to the 1998 Stark II proposed rule as well as several comments in response to Phases I and II of the rulemaking. The 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 refer-

ring physician, an individual that 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 DME (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.¹⁰²

The significant changes made in Phase II of the regulations focused on the “same building” test contained in the location requirement.¹⁰³ In Phase II of the regulations, CMS developed three new alternative “same building” tests that replaced 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.¹⁰⁴ Under all three tests, referring physicians or group practices 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 practices medicine and furnishes physician services for a minimum number of hours per week in that office (unfilled appointments, cancellations, and occasional gaps are permitted).

Phase III of the final rulemaking did not make any substantive changes to the in-office ancillary services exception, but, based upon statements made in the preamble commentary and in the MPPFS, it is clear that CMS is studying issues regarding this exception further and is considering narrowing the exception in some manner.¹⁰⁵ In Phase III, CMS notes that it is considering whether certain types of arrangements, such as those involving in-office pathology labs and sophisticated imaging equipment, should continue to be eligi-

ble for protection under the in-office ancillary services exception.¹⁰⁶

Academic Medical Centers Exception – 411.355(e)

Recognizing that academic medical centers (“AMCs”) often involve multiple affiliated entities that may make qualifying for an exception difficult, Phase I of the rulemaking created an exception for AMCs. The exception was created to protect payments to referring physician faculty of AMCs that meet certain conditions.¹⁰⁷ In an effort to address concerns with the AMC exception expressed by commenters in response to Phase I, Phase II made many revisions and clarifications to the AMC exception in order to make it easier to qualify for the exception.¹⁰⁸ For example, the definition of *academic medical center* was expanded to allow hospitals or health systems that sponsor four or more medical education programs to qualify as a component of an academic medical center.¹⁰⁹

Additionally, Phase II modified the exception to reflect that an AMC may have more than one affiliated faculty practice plan and that faculty practice plans can be affiliated with the teaching hospital, the medical school or the accredited academic hospital.¹¹⁰ In response to Phase I, commenters also asked for clarification with respect to what constitutes “substantial academic or substantial clinical teaching services” for purposes of the referring physician’s services. To provide clarity, Phase II added a safe harbor provision deeming any referring physician who spends at least 20 percent of his or her professional time or, in the alternative, eight hours per week providing academic services or clinical teaching services (or a combination), as fulfilling the requirement.¹¹¹ Phase II also added flexibility to the AMC exception by modifying the regulations to cover research money used for teaching, a core AMC function.¹¹²

The Phase III final rule adopts the Phase II rule with some minor clarifications.¹¹³ Phase III revises language in the academic medical exception to clarify that the total compensation from *each*

academic medical center component to a faculty physician must be set in advance and not determined in a manner that takes into account the volume or value of the physician’s referrals or other business generated by the referring physician within the academic medical center.¹¹⁴ Additionally, language was added to the exception to provide that for purposes of determining whether the majority of physicians on the medical staff of a hospital affiliated with an academic medical center consists of faculty members, the affiliated hospital must include or exclude all individuals holding the same class of privileges at the affiliated hospital.¹¹⁵

In Phase III, CMS also clarifies that nothing in the exception prohibits AMCs from compensating faculty members for the provision of indigent care or community care, provided that the funds do not derive from research funding; the total compensation paid to the referring physician is fair market value and satisfies the other requirements in Section 411.355(e)(1)(iii)(C); and the physician also performs the requisite clinical teaching or academic services under Section 411.355(e)(1)(i)(D).¹¹⁶

In Phase III, CMS also reminds commenters that the AMC exception is designed to supplement, not replace, other exceptions, such as the bona fide employment exception or the personal service arrangements exception.¹¹⁷ CMS further states that the definition and exception for indirect compensation arrangements are potentially applicable to arrangements involving AMCs and physicians.¹¹⁸

Implants Furnished by an Ambulatory Surgery Center (ASC) – 411.355(f)

In Phase I, CMS created an exception for implants furnished in an ASC.¹¹⁹ The exception is intended to allow physician owners of ASCs to order and perform surgeries that implant DME, prosthetics, or prosthetic devices. The exception was created because many implantable items are DHS, but are not bundled into the ASC composite rate. Without the exception there

would be no applicable ownership exception for many physician owners of ASCs who order and perform such surgeries (physician owners of rural ASCs could potentially qualify for the rural provider exception). Phases II and III did not make any changes to this exception, however, in Phase III, CMS makes clear that the exception does not apply if the physician submits the claim for the device, as Medicare payment rules require the ASC to bill for the item.¹²⁰

Intra-family Rural Referrals – 411.355(j)

In Phase II, CMS created a new limited exception for certain referrals from a referring physician to a DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient’s condition to furnish the DHS to the patient in his or her home (for DHS furnished to patients in their homes such as home health services or certain DME) or within 25 miles of the patient’s home (for DHS furnished outside of the patient’s home).¹²¹ Phase III modifies the exception to include an alternative distance test which is based on transportation time (45 minutes), not miles, from the patient’s home.¹²²

Exceptions to the Referral Prohibition Applicable to Ownership or Investment Interests – 411.356

Section 411.356 of the regulations sets forth various exceptions that are applicable only to ownership or investment interests. These exceptions cannot be used to protect a compensation arrangement. The exceptions listed in Section 411.356 include the: (a) publicly-traded securities exception; (b) mutual funds exception; and (c) specific providers exception (rural provider exception, hospitals located in Puerto Rico exception, and the whole hospital exception). This section of the article will focus on some of the exceptions contained in Section 411.356. For specific details

regarding a particular ownership or investment exception, see 42 C.F.R. § 411.356.

Publicly Traded Securities and Mutual Funds – 411.356(a) and (b)

The Stark law permits referring physicians to have an ownership in certain publicly traded securities and mutual funds.¹²³ The purpose of the publicly traded securities exception is to allow physicians or family members to acquire stock in large companies if the transaction does not particularly favor the physicians over other purchasers of stock.¹²⁴ Investment securities include shares or bonds, debentures, notes, or other debt instruments.¹²⁵ The Stark law also permits ownership of investments in mutual funds with total assets exceeding \$75 million at the end of the most recent fiscal year or the average of the last three fiscal years.¹²⁶

Phase II clarified that securities acquired by a referring physician (or an immediate family member) prior to a public offering will fit into the exception if they are available to the public at the time of any DHS referral.¹²⁷ Phase II also modified the definition of ownership and investment interest to reflect that stock options and convertible securities will be treated as compensation, rather than ownership, if they are received as compensation for services and will remain compensation until the time that they are exercised, at which time they convert to an ownership or investment interest.¹²⁸ CMS did not make any changes to Section 411.356(a) (2006) or Section 411.356(b) (2006) in the Phase III rulemaking.

Specific Provider – Rural Provider – 411.356(c)(1)

With respect to DHS furnished in rural areas, the Stark law permits referring physicians to have ownership or investment interests in providers that furnish DHS in a rural area, if substantially all of the DHS are furnished to individuals residing in the rural area.¹²⁹ For an 18-month period, which began on December 8, 2003, pursuant to

Section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”),¹³⁰ the rural provider exception was not applicable to specialty hospitals. The moratorium expired in June 2005.

Phase II of the regulations adopted the 1998 proposed rule that defined a “rural provider” as an entity that furnishes at least 75 percent of its total DHS to residents of a rural area.¹³¹ The proposed regulations defined a *rural area* as an area that is not an urban area as defined in Section 412.62(f)(1)(ii). Phase II adopted this definition and for ease of reference, Phase III added the term *rural area* to the definitions section of the regulations in Section 411.351. In Phase III, in response to a commenter, CMS notes that a physician who invests in a rural provider takes the risk that the area could later be reclassified as an urban area.¹³² As a practical matter, if this were to happen, the physician would have to divest his ownership or stop referring.

Specific Provider – Whole Hospital – 411.356(c)(3)

With respect to DHS provided by a hospital, an ownership or investment interest in a hospital is not a financial relationship within the meaning of the Stark law if the referring physician is authorized to perform services at the hospital. This exception, however, is strictly limited to ownership in the whole hospital, not merely a subdivision or part of the hospital.¹³³ As with the rural provider exception, the MMA 18-month moratorium on specialty hospitals was also incorporated into the whole hospital regulatory exception in Phase II of the rulemaking.¹³⁴

In Phase II of the rulemaking, CMS adopted the 1998 proposed rule which interpreted the requirement that DHS be “provided by the hospital” to mean that the services had to be provided at the hospital and not by another hospital-owned entity, such as a skilled nursing facility or home health agency.¹³⁵ Phase III did not change the whole hospital exception contained in 42 C.F.R. § 411.356(c)(3).

Although Phase III did not make any changes to the whole hospital exception, if the whole hospital exception is amended as proposed by the U.S. Representatives in Section 651 of the Children’s Health and Medicare Protection Act of 2007, opportunity for physician investment in hospitals would be limited and existing hospital investments would need to be reviewed to determine compliance with the new grandfathering criteria as set forth previously in this article.

Exceptions to the Referral Prohibition Applicable to Compensation Arrangements – 411.357

Section 411.357 sets forth various exceptions which are applicable only to compensation arrangements. Ownership or investment interests must be excepted under an applicable exception contained in Sections 411.355 or 411.356. The compensation exceptions listed in Section 411.357 include: (a) rental of office space; (b) rental of equipment; (c) bona fide employment relationships; (d) personal service arrangements; (e) physician recruitment; (f) isolated transactions; (g) certain arrangements with hospitals; (h) group practice arrangements with hospitals; (i) payments by a physician; (j) charitable donations by a physician; (k) nonmonetary compensation; (l) fair market value; (m) medical staff incidental benefits; (n) risk sharing arrangements; (o) compliance training; (p) indirect compensation arrangements; (q) referral services; (r) obstetrical malpractice insurance subsidies; (s) professional courtesy; (t) retention payments in underserved areas; (u) community-wide health information systems; (v) electronic prescribing items and services; and (w) electronic health records items and services. This section of the article will focus on some of the more commonly used exceptions and some of the exceptions which prompted commentary in Phase III of the rulemaking. For specific details regarding a particular compensation exception, see 42 C.F.R. § 411.357.

Rental of Office Space and Equipment – 411.357(a) and (b)

In order for an office space or equipment lease to meet the rental of office space or rental of equipment 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 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.¹³⁶ 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.¹³⁷

In the 1998 proposed regulations, CMS made several interpretations with respect to these lease arrangements including that the one-year term requirement permitted leases to be terminated “for cause,” provided that the parties do not enter into another lease until after the expiration of the original term.¹³⁸ Phase II modified the regulations to allow “without cause” terminations, provided that the parties do not enter into a new lease during the first year of the original term and the

new agreement complies with the exception.¹³⁹ In Phase II, CMS also modified the regulations to permit hold-over tenancies for a period of not more than six months.¹⁴⁰ Further, Phase II modified the exclusive use language to permit subleases.¹⁴¹ To prevent referring physicians or groups from circumventing the rules by setting up separate holding companies to act as the “lessor,” in Phase II, the regulations were modified to preclude sharing of rental space with the lessor or any person or entity related to the lessor.¹⁴²

Additionally, as part of Phase II, CMS modified the regulations to permit “per-click” payments for DHS referred by the referring physician as long as the payments are consistent with fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician, as defined in Sections 411.351 and 411.354.¹⁴³ Although Phase III does not make any substantive changes to the exceptions for rental of office space and equipment, as part of the July 2007 MPPFS, CMS is proposing to prohibit the use of “per-click” lease payments involving space and/or equipment leases in those situations where an entity owned by a physician leases space and/or equipment to another entity, and the physician subsequently refers patients to that other entity for services.¹⁴⁴

In response to public comment, in Phase III CMS clarifies that parties may not change the rental charges at any time during the term of the agreement and that parties wishing to do so must terminate the agreement and enter into a new agreement with different rental charges and/or other terms. However, the new agreement may be entered into only after the first year of the original lease term.¹⁴⁵ CMS also notes that parties may amend a lease agreement multiple times during or after the first year of its term so long as the rental charges are not changed and all other requirements of the exception are satisfied. CMS cautions, however, that changes to terms that are material to the rental charges (e.g., space leased) may cause the rental

charges to fall out of compliance with the “fair market value” and “volume or value of referrals” requirements.¹⁴⁶

Phase III also reminds readers that space leases are not eligible for the fair market value exception contained in Section 411.357(l).¹⁴⁷ In response to public comment regarding the application of the rental of office space and equipment lease exceptions to office-sharing arrangements between physicians, CMS states that the exclusive use provisions in the exceptions, in effect, require that space and equipment leases be for established blocks of time in connection with office-sharing arrangements.¹⁴⁸ CMS does not make any substantive changes to either exception in Phase III of the rulemaking.

Bona Fide Employment Relationships – 411.357(c)

Payments made by an employer to a physician (or immediate family member) pursuant to a bona fide employment relationship are excepted from Stark’s prohibition, if certain conditions are met. Specifically, the employment must be for identifiable services, the amount of compensation must be fair market value and not determined in manner that takes into account (directly or indirectly) the volume or value of referrals, and the employment agreement must be commercially reasonable, absent the referrals.¹⁴⁹

The 1998 proposed rule added additional limitations to the statutory requirements to restrict a physician’s ability to receive a productivity bonus based on his or her own productivity of DHS referrals, and to restrict compensation related to other business generated between the parties.¹⁵⁰ In Phase II, CMS did not adopt the 1998 limitation placed upon productivity bonuses as it was no longer relevant given that personally performed DHS are not considered *referrals* for purposes of Stark. Additionally, CMS noted that the exception does not preclude a productivity bonus based solely on personally performed supervision of services that are not DHS, as this type of bonus would not take into account the volume or value of DHS referrals.¹⁵¹

In Phase III, CMS does not make any changes to the bona fide employment relationships exception.

Personal Service Arrangements – 411.357 (d)

There is an exception in the Stark law, which is applicable to remuneration from an entity under an arrangement (or multiple arrangements) to a physician, immediate family member, or to a group practice, for personal service arrangements.¹⁵²

Phase II modified the one-year term provision to reflect that “without cause” provisions are permitted, provided that the parties do not enter into the same or substantially the same agreement during the first year of the original term.¹⁵³

The personal services exception contains an express provision allowing independent contractor physicians to be compensated under a physician incentive plan (“PIP”) with respect to services provided to individuals enrolled with the entity making the payments.¹⁵⁴ Phase II modified this PIP exception to clarify that it applies to downstream contractor arrangements related to health plan enrollees.¹⁵⁵ In a related matter, Phase III modifies the regulations slightly to refer consistently to the term *downstream contractor*, a term which is now defined in Section 411.351 and includes a first tier contractor and any individual or entity that has a subcontract directly or indirectly with a first tier contractor.¹⁵⁶

In Phase II, CMS also modified the regulations to allow parties the option to cross reference a master list of contracts, in addition to the existing option of incorporation of multiple agreements by reference.¹⁵⁷ A master list alternative will be satisfied if more than one master list is maintained and cross-referenced, so long as the several master lists, taken together, cover all of the contracts with the referring physician (or immediate family member).¹⁵⁸ Providers that take advantage of the master list option must be prepared to properly maintain the list(s) in a manner that preserves the

historical record if requested by the Secretary.¹⁵⁹

Phase III modifies the personal service arrangements exception to include a provision which permits a holdover personal service arrangement (services provided after the term of the contract expires) for up to six months.¹⁶⁰

Physician Recruitment – 411.357(e)

Under Stark, a hospital is permitted to pay a physician to induce the physician to relocate to the hospital’s geographic area in order for the physician to be a member of the hospital’s medical staff.¹⁶¹ Specifically, the recruitment arrangement must meet the following requirements: (1) the arrangement is set out in writing and signed by both parties; (2) the arrangement cannot be conditioned on the physician’s referrals; (3) the amount of remuneration under the agreement may not be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the physician; and (4) the physician must be allowed to establish staff privileges at any other hospital and to refer business to other entities.¹⁶²

In Phase II, CMS significantly modified the regulation in the following ways: (1) to be eligible for the exception, the physician must relocate his or her practice to the geographic area served by the hospital; (2) in order to meet the relocation requirement, the physician must: (a) relocate his or her practice a minimum of twenty-five (25) miles; or (b) at least seventy-five percent (75%) of the physician’s revenues must come from care provided to new patients; (3) residents and new physicians are eligible for the physician recruitment exception regardless of whether they actually move their practices; and (4) in addition to hospitals, the exception applies to federally qualified health care centers (“FQHC”).¹⁶³

In addition, Phase II also significantly modified the regulation with respect to recruitments made through existing group practices.¹⁶⁴ However,

because CMS was concerned about potential abuses, the accommodation for recruitment payments to group practices was narrowly tailored.¹⁶⁵ Under the Phase II rule, remuneration provided by a hospital (or FQHC) to a physician indirectly through payments to another physician, or physician practice, are permitted if the following criteria are met: (1) the written agreement is also signed by the party to whom the payments are made directly; (2) except for actual costs, the remuneration is passed directly through to, or remains with, the recruited physician; (3) in the case of an income guarantee made by the hospital to a physician who joins a local physician practice, costs allocated by the physician practice to the recruited physician may not exceed the actual additional incremental costs to the practice attributable to the recruited physician; (4) records of the actual costs and the passed through amounts are maintained for a period of at least 5 years; (5) the remuneration from the hospital is not determined in any manner that takes into account (directly or indirectly) the volume or value of any referrals (actual or anticipated) by the recruited physician or by the physician practice receiving the direct payments from the hospital (or any physician affiliated with that physician practice); (6) the physician practice receiving the hospital payments may not impose additional practice restrictions on the recruited physician, but may impose conditions related solely to quality considerations; and (7) the arrangement must not violate the anti-kickback statute and must comply with all relevant billing laws and regulations.¹⁶⁶

Phase III significantly relaxes the physician recruitment exception. Phase III modifies the exception to allow group practices to impose practice restrictions if they do not “unreasonably restrict” the recruited physician’s ability to practice in the geographic area served by the hospital. Notably, in Phase III, CMS observes that restrictions on moonlighting; prohibitions on soliciting patients, or employees; requiring the recruited physi-

cian to repay losses of his or her practice absorbed by the physician practice; and requiring liquidated damages if the physician leaves the practice and remains in the community, are all restrictions and prohibitions that CMS does not consider to have a substantial effect on the physician's ability to remain in the hospital's geographic service area. CMS noted, however, that a liquidated damages clause that provides for a "significant" or "unreasonable" payment may have a substantial effect on the physician's ability to remain in the service area, and may thus be disallowed.¹⁶⁷

In further efforts to relax the recruitment exception, Phase III permits rural clinics to use the exception.¹⁶⁸ It also deems the geographic area served by the hospital to be the area comprised of all of the contiguous zip codes from which the hospital's inpatients are drawn, when the hospital draws fewer than 75% of its inpatients from contiguous zip codes.¹⁶⁹ Phase III also adds a special option rule for rural hospitals in which the geographic area served by the hospital may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the geographic area served by the hospital may include noncontiguous zip codes.¹⁷⁰

Phase III adds a provision that allows rural hospitals to recruit physicians into an area outside of the geographic area served by the hospital if the Secretary of DHHS determines in an advisory opinion that the area has a demonstrated need for the physician.¹⁷¹ Also with respect to rural areas, Phase III adds a provision allowing groups in a rural area or a HPSA that recruit a physician to replace a retired, deceased, or relocated physician to either allocate the costs attributed by the recruited physician based upon (1) the actual additional incremental costs or (2) the lower of a per capita allocation or 20 percent of the practice's aggregate costs.¹⁷²

The Phase II rule had provided an exemption from the relocation requirement for residents and new physicians.¹⁷³ In the Phase III rule, CMS adds expands the exemption to apply to physicians who were employed full time by a federal or state bureau of prisons (or similar agency), the Department of Defense or Veterans Affairs, or facilities of the Indian Health Service. The new exemptions apply only if the physician did not maintain a separate private practice in addition to the full-time employment. Physicians may also be exempt from the relocation requirement if the Secretary deems in an advisory opinion that the physician has not established a medical practice.¹⁷⁴

CMS makes several other changes in the Phase III recruitment rule, clarifying that a physician must relocate his or her practice from outside the geographic area to a location inside the area and either (1) move his or her medical practice at least 25 miles; or (2) have a new medical practice. This clarification was made in response to commenters who perceived an inconsistency between the Phase II preamble commentary and the regulatory text. Some commenters were confused as to whether the recruited physician must relocate his or her practice from outside the geographic area into the area, or whether the physician may simply relocate within the geographic area so long as the physician moved his or her practice a minimum of 25 miles or had a new practice.¹⁷⁵

With respect to physician recruitment agreements involving physicians who join an existing practice, Phase III modifies the regulatory text to make clear that the requirements in 411.357(e)(4)(iii) are triggered by any income guarantee, whether gross income, net income, revenues, or some variation.¹⁷⁶

Nonmonetary Compensation – 411.357 (k)

The nonmonetary compensation exception was established in Phase I of the rulemaking and permits entities to provide physicians with nonmonetary

items or services (not cash or cash equivalents) that do not exceed an aggregate of \$300 per year.¹⁷⁷ In Phase II, CMS declined to adopt a higher threshold but modified the exception to include annual inflationary adjustments.¹⁷⁸ The nonmonetary compensation amount is adjusted annually for inflation. The annual amount increases are available on the CMS physician self-referral website at www.cms.hhs.gov/PhysicianSelfReferral.¹⁷⁹

Phase III makes two substantive changes to the exception by: (1) allowing physicians to repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception; and (2) allowing entities without regard to the \$300 dollar limit to provide one medical staff appreciation function (such as a party) for the entire medical staff per year. Any gift or gratuities provided in connection with the medical staff appreciation function, however, are subject to the \$300 limit. The new cure provision only applies to situations in which the entity inadvertently provides excess nonmonetary compensation to the physician.¹⁸⁰

Fair Market Value – 411.357(l)

The 1998 Stark II proposed rule set forth a new exception for compensation arrangements that reflect fair market value.¹⁸¹ The Phase I rule finalized the 1998 fair market value proposal.¹⁸² The exception protects compensation from a DHS entity to a physician, an immediate family member of a physician, or a group of physicians for the provision of items or services by the physician or group to the DHS entity if: (1) the arrangement is set out in writing signed by the parties and describes the items or services; (2) the writing sets forth a timeframe for the arrangement; (3) the writing specifies the compensation which must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician; (4) the arrangement is commercially reasonable; and (5) it does not violate the anti-kickback statute or other laws governing

billing or claims submission or involve the promotion of any arrangement that violates federal or state law.¹⁸³

Phase III modifies the fair market exception to allow the exception to be used with respect to compensation provided to a physician from an entity and to compensation provided to an entity from a physician. CMS also clarifies in the regulatory text that the fair market value exception cannot be used to protect office leases.¹⁸⁴ CMS also reaffirms its earlier position that the fair market value exception is not applicable to physician requirement arrangements.¹⁸⁵

Compliance Training – 411.357(o)

In Phase I, CMS recognized the benefit of hospitals offering compliance training programs for their staff physicians or for physicians in the community. As a result, CMS created an exception for hospitals that provided compliance training to physicians in the hospital's local community or service area, provided the training is held in that area.¹⁸⁶ Phase II modified the exception to clarify that all entities (not just hospitals) can provide compliance training to physicians.¹⁸⁷ Although in Phase II CMS stated that compliance training does not include continuing medical education (CME), Phase III amends the compliance training exception to cover compliance training programs that involve CME credit so long as the compliance training is the primary purpose.¹⁸⁸

Indirect Compensation Arrangements – 411.357(p)

Phase I of the rulemaking established a new exception for indirect compensation arrangements.¹⁸⁹ If a relationship meets the three-part indirect compensation arrangement definition, then it must be structured to comply with the indirect compensation arrangements exception. In order for an indirect compensation arrangement to meet this exception, the following requirements must be met: (1) the compensation received by the referring physician (or immediate family member) from the person or entity in the chain of financial

relationships with which the referring physician (or immediate family) has a direct financial relationship is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS; (2) the compensation arrangement between the person or entity in the chain with which the referring physician has a direct relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement (except in the case of a bona fide employment relationship); and (3) the compensation arrangement does not violate the anti-kickback statute, or any federal or state law or regulation governing billing or claims submission.¹⁹⁰

Phase II made slight modifications to the indirect compensation definition to clarify that the special rules on unit-based compensation do not apply when analyzing whether a relationship meets the three part indirect compensation definition but they do apply when analyzing whether an indirect compensation arrangement falls within the indirect compensation arrangement exception.¹⁹¹

Phase III of the final rulemaking does not make any substantive changes to the exception. Under the revised rules regarding compensation relationships, however, physicians will now be “standing in the shoes” of their group practices, so many arrangements that would have been considered indirect compensation arrangements will now be deemed to be direct relationships, which cannot use the indirect compensation exception.¹⁹²

Obstetrical Malpractice Insurance Subsidies – 411.357(r)

In Phase I of the rulemaking, CMS solicited comments on creating exceptions for arrangements that fit squarely within an anti-kickback “safe harbor.”¹⁹³ In Phase II, CMS created an exception for arrangements that fit in the anti-kickback safe harbor for obstetrical malpractice insurance subsidies.¹⁹⁴ Phase III does not modify this exception,

however, in the July 2007 MPPFS, CMS proposes to amend the exception to remove the incorporation of the safe harbor for malpractice insurance (1001.952(o)) and to include more flexible criteria.¹⁹⁵ In Phase III, CMS does state that in addition to the obstetrical malpractice insurance subsidies exception, there are several compensation exceptions (e.g., fair market value, bona fide employment, or personal services) that potentially permit DHS entities to provide assistance with malpractice insurance.¹⁹⁶

Professional Courtesy – 411.357(s)

In Phase II, CMS created 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.¹⁹⁷ Phase II defined professional courtesy as the provision of free or discounted healthcare items or services.¹⁹⁸ To qualify for the professional courtesy exception, the arrangement must meet the following conditions: (1) the professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the entity's local community without regard to the volume or value of referrals generated between the parties; (2) the healthcare items and services provided are of a type routinely provided by the entity; (3) the professional courtesy policy is set out in writing and approved in advance by the governing body of the healthcare provider; (4) the professional courtesy is not offered to any physician (or immediate family member) who is a Federal healthcare program beneficiary, unless there has been a good faith showing of financial need.; (5) if the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of that reduction so that the insurer is aware of the arrangement; and (6) the arrangement does not violate the anti-kickback statute or billing or claims submission laws or regulations.¹⁹⁹

Phase III deletes the provision of the exception which requires an entity to

notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation. Despite the deletion, however, CMS states that it believes it is prudent practice to provide notification and may still be required by some insurers. Phase III also modifies the exception to clarify that it applies only to hospitals and other providers with formal medical staffs, and not to suppliers, such as laboratories or DME companies. In the Phase III preamble commentary, CMS states that it considers a group or other physician practice to be an entity with a formal medical staff that can utilize the professional courtesy exception.²⁰⁰

Retention Payments in Underserved Areas – 411.357(t)

Phase II established a narrow exception for certain retention payments made to physicians with practices in HPSAs.²⁰¹ The exception applies to retention payments made to a physician with a practice located in a HPSA who has a firm written recruitment offer from an unrelated hospital (or FQHC) that specifies the remuneration being offered and that would require the physician to move the location of his or her practice at least 25 miles and outside of the geographic area served by the hospital (or FQHC). Additionally, the retention payment must be the lower of: (1) the difference between the physician's current income from physician and related services in the recruitment offer (over no more than a 24 month period); or (2) the reasonable costs the hospital (or FQHC) would otherwise have to expend to recruit a new physician to the geographic area.²⁰²

Phase III modifies the exception in several respects. It expands the exception by allowing rural health clinics to make retention payments.²⁰³ Phase III also revises the exception to permit a hospital, rural health clinic, or FQHC to offer assistance to a physician who does not have a bona fide written offer of recruitment or employment if the physician certifies in writing that he or she has a bona fide opportunity for future employment which would require relocation of

his or her medical practice at least 25 miles to a location outside of the geographic area. In circumstances in which the physician provides written certification instead of a bona fide written offer, the retention payment may not exceed the lower of: (1) an amount equal to 25 percent of the physician's annual income; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician. Under this new certification provision, the physician certification must contain at least: (1) details regarding the steps taken to effectuate the employment opportunity; (2) details of the employment opportunity; (3) certification that the future employer is not related to the hospital making the payment; (4) the date of the anticipated relocation; and (5) information sufficient to verify the certification.²⁰⁴

Phase III further expands the exception to permit retention payments that otherwise satisfy the requirements of the exception when: (1) the physician's current medical practice is located in a rural area, a HPSA, or an area of demonstrated need determined by the Secretary of DHHS in an advisory opinion; or (2) at least 75 percent of the physician's patients either reside in medically underserved area or are members of a medically underserved population.²⁰⁵

In response to commenters who questioned why the retention exception requires a retention payment to be contingent on an offer from a hospital, in Phase III, CMS amends the regulatory text to allow retention payments if a physician has a written offer from a hospital, academic medical center, or physician organization (which is newly defined in Phase III). The offer cannot be from a entity that is related to the hospital, rural health clinic, or federally qualified health care center that is making the retention payment.²⁰⁶

Electronic Prescribing Items and Services and Electronic Health Records Items and Services – 411.357(v) and (w)

In October 2005, CMS published a notice of proposed rulemaking creating

an exception for prescribing technology and an exception for electronic health records software and information technology and training services.²⁰⁷ After public comment on the exceptions, CMS published a final rule on August 8, 2006.²⁰⁸ The exception for electronic prescribing items and services appears in 411.357(v) and the exception for electronic health records software and information technology and training services appears in 411.357(w).

Reporting Requirements – 411.361

The Stark law contains a reporting provision requiring all entities to submit certain information to the Secretary of DHHS.²⁰⁹ The Phase II rule required 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 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; (3) the covered services furnished by the entity; and (4) the nature of the financial relationship (including the extent or value of the interest).²¹⁰

A "reportable financial relationship" means any ownership or investment interest (as defined in 411.354(b)) or any compensation arrangement (as defined in 411.354(c)), except for ownership or investment interests that satisfy the exceptions set forth in 411.356(a) or (b) regarding publicly traded securities and mutual funds.²¹¹ 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.²¹²

The reporting requirements state that, upon request, entities must submit the required information within the time period specified by the request. Entities will be given at least 30 days from the date of request to provide the information. Any person who is required, but fails to submit information concerning his or her financial relationships, is subject to a civil monetary penalty of up to \$10,000 for each day after the deadline until the information is submitted.²¹³

Phase II also modified the reporting requirements to specify that the information required is only that information that the entity knows or should know 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 under the Medicare and Medicaid programs.²¹⁴

Phase III of the rulemaking does not make any substantive changes to the reporting requirements at 411.361. However, the exception is modified slightly to account for the transition of the UPIN to the NPI.²¹⁵

In response to public comment, in Phase III, CMS states that much of the information that it may receive pursuant to 411.361 will be exempt from disclosure under the Freedom of Information Act (FOIA)²¹⁶ and prohibited from disclosure by the Trade Secrets Act.²¹⁷ But, when CMS receives a request for information that has been reported, CMS is required to evaluate whether the particular information is exempt or prohibited from disclosure.²¹⁸

The reporting requirements at 411.361 are particularly relevant in light of the recent mandate sent by CMS to 500 selected hospitals. The purpose of the CMS mandate is to collect information that will subsequently be used to analyze all investment interests or compensation arrangements between each of the 500 hospitals and their respective physicians. CMS is requiring that the information be submitted within 45 days and reminds hospitals of

the \$10,000 civil monetary penalty per day beyond the deadline. The disclosure notice is located on the CMS self-referral website at www.cms.hhs.gov/PhysicianSelfreferral.

Advisory Opinions Relating to Physician Referrals – 411.370-411.389

For information regarding the CMS advisory opinion process, please see 42 C.F.R. §§ 411.370-389.

Conclusion

This article is intended to provide a “full picture” of the Stark physician self-referral prohibition. It addresses the highlights of Phase III of the final rulemaking, identifies other proposals that may impact the Stark regulations in the future, and provides a comprehensive summary of the overall Stark regulatory scheme as finalized by the Phase III final rule. Although this article is meant to be a comprehensive “full picture” of Stark, it does not cover every aspect of the regulations. Attorneys should carefully scrutinize the statute, regulations, and preamble commentary before attempting to advise a client regarding relationships that potentially fall within the ambit of Stark .

Andrew B. Wachler is the principal of Wachler & Associates, P.C. He graduated Cum Laude from the University of Michigan in 1974 and Cum Laude from Wayne State University Law School in 1978. Mr. Wachler is a member of the State Bar of Michigan, Healthcare Law Section (Health Providers Subcommittee, past member Healthcare Law Section Council), American Bar Association, Health Care Law Section, and the American Health Lawyers Association.

Adrienne Dresevic is a partner with Wachler & Associates, P.C. Ms. Dresevic graduated Magna Cum Laude from Wayne State University Law School in 2002 where she was elected as a member of the Order of the Coif. Ms. Dresevic is a member of the State Bar of Michigan, Health Law Section and the American Health Lawyers Association. Ms. Dresevic

concentrates her practice on Stark; Fraud and Abuse; healthcare compliance; and Medicare, Medicaid, Blue Cross Blue Shield and other third party payer audits.

Endnotes

- ¹ Social Security Act § 1877, codified at 42 U.S.C. § 1395nn.
- ² 72 Fed. Reg. 51012- 51099 (2007).
- ³ 69 Fed. Reg. 16054 (2004). See rulemaking history, *infra*, part II.
- ⁴ 42 U.S.C. § 1395nn.
- ⁵ 60 Fed. Reg. 41923 (1995).
- ⁶ 63 Fed. Reg. 1659 (1998).
- ⁷ 66 Fed. Reg. 856 (2001).
- ⁸ 69 Fed. Reg. 16054 (2004).
- ⁹ 60 Fed. Reg. 41914 (1995).
- ¹⁰ 72 Fed. Reg. 51012 (2007).
- ¹¹ 72 Fed. Reg. 51013 (2007).
- ¹² For the sake of simplicity, references throughout this article to sections of the Code of Federal Regulations (C.F.R.) amended by the Phase III final rule are to the text to be codified, as amended, except as otherwise specifically noted by date, e.g., “42 C.F.R. § xxx.yyy (2006).”
- ¹³ 70 Fed. Reg. 59182 (2005), 71 Fed. Reg. 45140 (2006).
- ¹⁴ 72 Fed. Reg. 51015-51016 (2007).
- ¹⁵ 72 Fed. Reg. 51017-51018 (2007), 42 C.F.R. § 411.351.
- ¹⁶ 66 Fed. Reg. 871-872 (2001).
- ¹⁷ 72 Fed. Reg. 51019-51020 (2007).
- ¹⁸ 72 Fed. Reg. 51022-51024 (2007), 42 C.F.R. § 411.352 (i).
- ¹⁹ 72 Fed. Reg. 51061-51063 (2007), 42 C.F.R. § 411.354(a)(2), 42 C.F.R. § 411.354(c) (1)(i)-(ii), 42 C.F.R. § 411.354(c)(3)(i)-(ii).
- ²⁰ 72 Fed. Reg. 51027, 51043 (2007), 42 C.F.R. § 411.354(b)(3)(v).
- ²¹ 72 Fed. Reg. 51032-51035 (2007).
- ²² 72 Fed. Reg. 51036-51038 (2007), 42 C.F.R. § 411.355(e).
- ²³ 72 Fed. Reg. 51039-51041 (2007), 42 C.F.R. § 411.355(j).
- ²⁴ 72 Fed. Reg. 51045-51047 (2007), 42 C.F.R. § 411.357(d).
- ²⁵ 72 Fed. Reg. 51047-51054 (2007), 42 C.F.R. § 411.357(e).
- ²⁶ 72 Fed. Reg. 51058-51059 (2007), 42 C.F.R. § 411.357(k).
- ²⁷ 72 Fed. Reg. 51059-51060 (2007), 42 C.F.R. § 411.357(l).
- ²⁸ 72 Fed. Reg. 51061(2007), 42 C.F.R. § 411.357(o).
- ²⁹ 72 Fed. Reg. 51064-51065, 42 C.F.R. § 411.357(s).

- 30 72 Fed. Reg. 51065-51068 (2007), 42 C.F.R. § 411.357(t).
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- 33 72 Fed. Reg. 38181-38182 (2007).
- 34 72 Fed. Reg. 38182-38183 (2007).
- 35 72 Fed. Reg. 38184 (2007).
- 36 See discussion under part V, *infra*.
- 37 72 Fed. Reg. 38186-38187 (2007).
- 38 72 Fed. Reg. 38184 (2007).
- 39 72 Fed. Reg. 38183-38184 (2007).
- 40 72 Fed. Reg. 38169-38171 (2007).
- 41 72 Fed. Reg. 38180, 38182-38185 (2007).
- 42 H.R. 3162 § 651 Children's Health and Medicare Protection Act of 2007.
- 43 Robert Pear, *Senate Passes Children's Health Bill, 68-31*, New York Times, August 3, 2007, available at <http://www.nytimes.com/2007/08/03/washington/03health.html?ex=1343793600&en=3c6c76fb95e1d11d&ei=5088> (last visited September 12, 2007).
- 44 *Disclosures of Investments and Compensation Relationships: CMS to Require Hospitals to Complete Report Concerning Investment Interests and Compensation Relationships with Physicians*, available at http://www.cms.hhs.gov/PhysicianSelfReferral/O5a_Disclosure.asp (last visited September 12, 2007).
- 45 42 C.F.R. § 411.361(c) (2006).
- 46 42 C.F.R. § 411.361(d) (2006).
- 47 42 C.F.R. § 411.361(f) (2006).
- 48 72 Fed. Reg. 51012 (2007).
- 49 42 U.S.C. § 1395nn.
- 50 72 Fed. Reg. 51034-51035 (2007), 42 C.F.R. § 411.350.
- 51 42 C.F.R. § 424.80.
- 52 72 Fed. Reg. 51035 (2007), 42 C.F.R. § 411.351.
- 53 42 C.F.R. § 411.351.
- 54 66 Fed. Reg. 946 (2001), 42 C.F.R. § 411.351.
- 55 42 C.F.R. § 411.351.
- 56 72 Fed. Reg. 51021 (2007).
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- 60 42 U.S.C. § 1395nn(h)(6).
- 61 Current Procedural Technology (CPT) codes are used to identify medical services and procedures performed by physicians. Healthcare Financing Administration Common Procedure Coding System (HCPCS) is a standard alphanumeric coding system primarily representing supplies and non-physician services which are not covered by the CPT codes.
- 62 66 Fed. Reg. 922-924 (2001).
- 63 For the current list, see 71 Fed. Reg. 70247-70251 (December 1, 2006).
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- 77 42 C.F.R. § 411.352(i) (2006).
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- 91 66 Fed. Reg. 864-870 (2001), 42 C.F.R. § 411.354 (c) (2) (2006) and 42 C.F.R. § 411.357(p) (2006).
- 92 69 Fed. Reg. 16061 (2004), 42 C.F.R. § 411.354(b)(5)(i)(B) (2006).
- 93 72 Fed. Reg. 51027 (2007), 42 C.F.R. § 411.354(b)(3)(v).
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