

An artistic painting featuring a bridge with a wooden railing and dark supports, arching over a bright, glowing yellow and orange light source. On either side of the bridge are two large, dark, textured faces in profile, facing each other. The background is a mix of blue and green tones with some faint, illegible text. The overall style is expressive and textured.

AMC Mission Support and Community Outreach Programs in the Aftermath of the Stark II, Phase III Regulations

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On September 5, 2007, the Centers for Medicare and Medicaid Services (CMS) published the Stark II, Phase III Regulations¹—a final rule that was the latest iteration in a long series of regulations implementing the federal physician self-referral statute.² The original legislation (Stark I) barred a physician from referring Medicare patients to clinical labs for the furnishing of clinical laboratory services if the physician (or an immediate family member) had a defined financial relationship with the lab and none of the statute's exceptions applied. The labs, in turn, were prohibited from billing for improperly referred services.³

In 1993, Congress expanded the reach of the Stark statute to cover nearly a dozen “designated health services” in amendments dubbed “Stark II.”⁴ CMS promulgated regulations clarifying Stark II and identifying new regulatory exceptions on January 4, 2001 (Stark II, Phase I Regulations).⁵ On March 26, 2004, CMS published an Interim Final Rule (Stark II, Phase II Regulations), implementing substantial revisions to the regulations and promising further clarifications and revisions.⁶ The recently published Phase III Regulations include modifications that are likely to have significant implications for the provider community, including academic medical centers (AMCs).⁷ The Stark I and Stark II statutes and their implementing regulations are collectively referred to in this article as the “Stark Law.”

In this article, we describe several organizational models common to AMCs, the types of financial arrangements most often relevant to AMCs, the exceptions AMCs typically rely on to pursue those arrangements, and the impact of recent and proposed regulatory amendments on the ability of AMCs to continue existing relationships with referring physicians or pursue new ones.

I. Mission Support and Community Outreach Arrangements

It is a truism that “if you’ve seen one academic medical center, you’ve seen one.” The Association of Academic Medical Centers (AAMC) represents 126 U.S. medical schools and nearly 400 major teaching hospitals, including 98 affiliated health systems and 68 Veterans Affairs medical centers,⁸ each organized somewhat differently.⁹ To simplify our analysis, we group AMC models into four broad categories:

Type 1: Fully Integrated

A single corporate entity that consists at least of a university or medical school, a teaching hospital, and a faculty practice plan (FPP).

Type 2: Partially Integrated (School + Hospital or School + FPP)

An integrated delivery system that consists at least of: (1) a university or medical school and teaching hospital plus a separately incorporated FPP; or (2) a university or medical school and FPP plus a separately incorporated teaching hospital.

Type 3: Independent

A group of independent but affiliated entities including at least a university or medical school, a teaching hospital, and a FPP.

In each of these models, FPP physicians provide professional and administrative services to the hospital. Community physicians unaffiliated with the FPPs may or may not practice at the hospital or provide administrative services there.

A. MISSION SUPPORT

Academic medical centers serve three related but very different missions: education, research, and clinical care. The tuition, fees, grants, and charitable gifts that many assume support academic operations—education and

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research—do not fully subsidize the costs of those activities. Healthcare delivery can generate profits or margins, however, and has long served as an important source of support for medical schools and their faculty.¹⁰ Threats to traditional sources of academic funding, including flat or reduced government and industry grant funding, redirection of research funding from AMCs to community hospitals and private practices (and, in some cases, offshore), and reductions in graduate medical education payments, are likely to make clinical support increasingly important in the future.

Financial arrangements among AMC components are often complex¹¹ and can take countless forms. For example, AMC hospitals often contract with FPPs to obtain administrative or professional services necessary to operate the hospitals and deliver care to patients. In many cases, however, hospitals and FPPs simply donate or transfer significant assets or funds to support their affiliated medical schools’ teaching and research missions. Until Phase III, AMCs often relied upon both the AMC exception and the more flexible indirect compensation arrangements exceptions to comply with the Stark Law. AMCs also benefited from three favorable advisory opinions (AOs) issued by the US Department of Health and Human Services, Office of Inspector General (OIG) on mission

support arrangements.¹² In each case, OIG reasoned that: (1) the proposed transaction would be among components of an AMC that historically had shared a common mission in training physicians for, and providing quality medical care to, local residents; and (2) the AMC certified it would take a number of steps to insulate physician judgment and income from pressure to refer to the hospital. These included imposition of a bar on tracking referrals, and a commitment that payments to physicians from all AMC sources would not be related to the volume or value of referrals to the hospital or other parties and would be consistent with fair market value in arms-length transactions. In AO 00-6 and AO 05-11, OIG further observed that the proposed donation would confer a community benefit; in AO 02-11, OIG found that the donation was consistent with state legislation requiring the hospital to support the AMC's academic mission. In many ways, the AMC exception that CMS promulgated in Phase II reflects the OIG's favorable rulings in these advisory opinions.

B. COMMUNITY OUTREACH

Many AMCs make significant efforts to reach out beyond their immediate service areas to provide needed clinical services, support their teaching missions, and offer opportunities to participate in clinical trials. Some do this simply by allowing their faculty physicians to practice independently at affiliated or unaffiliated community hospitals or other facilities. Many, however, contract with various providers and other organizations to provide administrative and professional services and in some cases to secure training opportunities for medical students and residents or facilitate the conduct of clinical trials.

These outreach arrangements are organized in a variety of ways. AMCs may enter into joint ventures with otherwise unaffiliated providers to

expand into new markets or develop new services. They may contract with healthcare facilities unable to recruit the necessary subspecialists on their own to provide administrative services—such as medical directorships, quality improvement, or peer review services. FPPs also may provide professional services off campus in return for a flat fee from the recipient provider (to whom the FPPs then reassign their right to payment), or under a contractual arrangement that permits them to bill patients and payors directly for their professional services. These arrangements range in scope from complete staffing of whole departments or even hospitals to occasional clinics that allow patients in need of subspecialty services to access those services closer to home. In some cases, FPPs or their members may provide free or reduced cost services to federally qualified health centers and other free or heavily subsidized clinics providing healthcare to underserved or at-risk populations.

C. IMPLICATIONS

Mission support arrangements and community outreach initiatives implicate the Stark Law. AMCs in the past have relied on Stark's indirect compensation and academic medical center exceptions to facilitate compliance. But recent changes in the rules, including provisions that collapse group practices with their individual physician members, may threaten future relationships.¹³ Together with the proposed physician fee schedule (PFS) rules, they also may eliminate the ability to pursue transactions specifically approved by OIG in advisory opinions under the anti-kickback statute, including some gainsharing arrangements.

We discuss below the Stark Law and regulations before and after publication of Phase III and the proposed PFS rules, new challenges faced by some AMCs, and steps AMCs may take to address those challenges.

III. The Stark Law: A Brief Overview

A. REFERRAL AND BILLING PROHIBITIONS

The Stark Law prohibits a “physician” from “referring” patients to an “entity” for the “furnishing” of “designated health services” (DHS) covered by Medicare if the physician (or an immediate family member) has a “financial relationship” with the entity, unless an exception applies.¹⁴ The Stark Law also prohibits the furnishing entity from submitting a claim for reimbursement or otherwise billing Medicare or any other person or entity for improperly referred DHS.¹⁵

With a few very narrow exceptions, CMS takes the position that the “furnishing entity” (or “DHS entity” for purposes of this article) is the entity that is paid by CMS (or its contractors) for the DHS.¹⁶ The Proposed 2008 PFS would have expanded this definition to include entities that “perform” the DHS.¹⁷ The Final 2008 PFS did not make this change, although it may reappear in a future rulemaking.¹⁸

B. FINANCIAL RELATIONSHIPS

The *sin qua non* of a Stark Law violation is the existence of a “financial relationship” between the referring physician (or his or her immediate family member) and the DHS entity. A financial relationship may take one of two forms: (1) an ownership or investment interest in the entity, or (2) a compensation arrangement with the entity.¹⁹ According to the Stark regulations, a compensation arrangement may be “direct” or “indirect.”²⁰

C. SCIENTER

In contrast to the Anti-Kickback Law,²¹ the Stark Law does not have a scienter, or “state of mind,” requirement. The inquiry is solely whether a physician has “referred” a Medicare

patient to an “entity” with which the physician has a “financial relationship” for the “furnishing” of DHS. If the answer is “yes,” then the Stark Law has been violated—regardless of the parties’ intentions or motivations—unless an exception applies.

D. EXCEPTIONS

The Stark Law contains numerous exceptions, which, if satisfied in full, permit a physician to refer Medicare patients to a DHS entity notwithstanding an underlying financial relationship between the two parties. According to CMS, in the case of an indirect compensation arrangement, the referring physician and DHS entity may not rely on any of the Stark Law’s *direct* compensation arrangement exceptions. Rather, the parties must satisfy either (1) an all purpose exception (e.g., the in-office ancillary services exception) or (2) the indirect compensation arrangements exception.²²

IV. Compensation Arrangements: Pre-Phase III Definitions

A. DIRECT COMPENSATION ARRANGEMENTS

Under a test established in Phase I, a physician had a “direct” compensation arrangement with an entity if remuneration passed between the physician and the entity without any intervening persons or entities.²³ Prior to Phase III,²⁴ physician practices or groups (except solo practitioners’ professional corporations) were considered intervening entities. Thus, for example, a physician employed (and paid a salary) by a FPP, which, in turn, contracted with (and received remuneration from) an affiliated teaching hospital to furnish services to the teaching hospital, had a “direct” compensation arrangement with the FPP, but not with the teaching hospital. For the reasons discussed below, however, the

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physician may have had an “indirect” compensation arrangement with the teaching hospital.

B. “INDIRECT” COMPENSATION ARRANGEMENTS

CMS first defined the phrase “indirect compensation arrangement” in Phase I. Specifically, CMS adopted a three-prong definition.

First, there must be an “unbroken chain” of at least two financial relationships between the referring physician and the DHS entity.²⁵ That is, there must be one or more intervening entities in the unbroken chain of financial relationships between the physician and the DHS entity. Thus, a medical directorship agreement between a teaching hospital and a FPP member results in a direct compensation arrangement: Hospital → Physician. If, however, as is typically the case, the teaching hospital executes an agreement with the FPP, pursuant to which one or more faculty members perform medical directorship services for the teaching hospital, then the relationship between the physician(s) and the teaching hospital might be indirect (assuming the other two prongs of the indirect compensation arrangements definition, discussed below, were satisfied), but not direct. The financial relationship

is indirect because the FPP serves as an intervening entity in an unbroken chain of financial relationships: Hospital → FPP → Physician. *Second*, the physician’s aggregate compensation under the arrangement must vary with, or otherwise reflect,²⁶ the volume or value of referrals or other business generated by the referring physician for the furnishing entity.²⁷ If the aggregate compensation received by the physician does *not* vary with or otherwise reflect the volume or value of his or her referrals to, or other business generated for, the furnishing entity—then there is no “indirect” compensation arrangement between the physician and the entity and the physician is free to refer Medicare patients to the entity for DHS without triggering the Stark Law’s referral or billing prohibitions. In determining whether this aggregate compensation test is satisfied, the analysis focuses on the direct *compensation* arrangement in the chain of unbroken relationships that is closest to the referring physician, which in the chain of Hospital → FPP → Physician is the compensation paid by the FPP to its physician-employee.²⁸

Third, the entity furnishing the DHS must have actual knowledge (or act in reckless disregard or deliberate ignorance) of the fact that the referring physician’s aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by him or her for the entity.²⁹

V. Compensation Arrangements Under Phase III

Of all the Phase III changes, the most significant—for many providers—relates to the circumstances that give rise to a *direct* versus an *indirect* compensation arrangement, and the exceptions that may be utilized to protect such arrange

ments from the Stark Law's referral and billing prohibitions. These changes are discussed below.

A. "DIRECT" AND "INDIRECT" COMPENSATION ARRANGEMENTS: POST-PHASE III DEFINITIONS AND IMPLICATIONS

Phase III changes the definitions of both direct and indirect compensation arrangements in a material, and, for AMCs, potentially dramatic, manner. Under the new regulations, "[a] physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity is his or her physician organization."³⁰ Thus from now on, and common law principles notwithstanding, a physician is deemed to "stand in the shoes" of his or her physician organization.³¹ As a practical matter, the "stand in the shoes" doctrine is a legal fiction pursuant to which the physician *members, employees, and independent contractors* of a physician organization are deemed to have the identical *compensation* arrangements (with the same parties and under the same terms) as the physician organization itself.³²

Thus, assume, by way of example, that a community hospital enters into a professional services agreement with a FPP, pursuant to which two of the FPP's vascular surgeon employees will staff and oversee the hospital's vascular clinic one-day-a-week in return for a fee. Historically, this set of arrangements gave rise to the following chain of unbroken financial relationships: Community Hospital → FPP → Vascular Surgeons; it also gave rise to an unbroken chain of financial relationships between the hospital and every other physician employee or contractor of the FPP. In the aftermath of the Phase III Regulations, as published on September 5, 2007, not only would the two vascular surgeons be deemed to have a direct compen-

sation arrangement with the hospital, but that arrangement also would be attributed to every other member of the FPP, thereby placing all of their referrals at risk.

1. "Physician Organization" Defined

As published, the Phase III Regulations defined a "physician organization" to include a physician, his/her professional corporation, a physician practice or a group practice.³³ Some early commentary suggested this definition may not apply to practices that do not have physician owners, such as medical foundations and nonprofit FPPs. The Regulations, however, did not appear to support that interpretation, suggesting, instead, that the definition applied to all physician clinical practices regardless of their corporate structure, at least where the clinical practice is a free-standing organization such as a separately incorporated FPP. As noted above, some FPPs are not organized as separate entities, but rather are a part of larger, multi-purpose educational institutions such as state universities. It was less clear whether CMS intended to have all of the physicians who are employed by a state university, for example, "stand in the shoes" of the university, which may include (but ultimately is a lot more than) a physician organization.

Prompted by dozens of informal inquiries regarding the application of the "stand in the shoes" doctrine to AMCs and certain other section 501(c)(3) organizations, CMS issued a notice on November 9, 2007, which postponed the application of the doctrine with respect to AMCs and integrated 501(c)(3) health systems for a one-year period—i.e., until December 4, 2008.³⁴

2. Other Intervening Entities

Importantly, the "stand in the shoes" doctrine does not eliminate all indirect compensation arrangements. Indirect compensation arrangements may continue to exist where there is an

intervening entity between the referring physician and the DHS entity that is not a physician organization.³⁵ CMS explains that this may occur in unbroken financial chains that involve a physician organization (e.g., Hospital → Health System → FPP → Physician) or in financial chains that simply do not involve a physician organization (e.g., Hospital → Health System → Physician).³⁶ CMS remains concerned, however, that arrangements that interpose intervening entities other than physician organizations between the referring physician and the DHS entity are subject to abuse.³⁷

As a practical matter, the fact that the "stand in the shoes" doctrine has not struck the death knell for all indirect compensation arrangements may not mean much for AMCs whose components routinely make academic and mission support payments. Assume a partially integrated AMC with a separately incorporated FPP that employs several hundred physicians. Assume further that the teaching hospital historically has furnished the university with mission support, which the school, in turn, has funneled, in whole or in part, to the FPP, thereby giving rise (assuming the "stand in the shoes" doctrine is applied to AMCs without change on December 4, 2008) to the following unbroken chain of financial relationships: Hospital → School → FPP → Physicians.

Prior to the Phase III Regulations, the analysis of whether this chain of financial relationships gave rise to an indirect compensation arrangement between the FPP physicians and the teaching hospital would have focused on the closest compensation arrangement to the referring physician. Thus, the inquiry would have been whether the aggregate compensation paid by the FPP to its physicians varied with, or otherwise reflected, the volume or value of referrals/other business generated for the teaching hospital. The answer more often than not was "no," thereby ending the analysis.

Under Phase III (if applied to AMCs), however, the FPP physicians will stand in the shoes of the FPP, meaning that the closest direct compensation arrangement to the referring physicians becomes the mission support payment. Although the literal language of the regulation suggests that perhaps the “stand in the shoes” doctrine applies only to the first prong of the indirect compensation arrangements definition,³⁸ and does not extend to the second prong of the definition where the focus is on the aggregate compensation received by the referring physician, CMS has (informally) stated that the “stand in the shoes” doctrine applies for the entire definition of indirect compensation and the indirect compensation arrangements exception.³⁹ Given that the mission support payment typically is not for a specific service nor consistent with fair market value, it may be difficult to argue that it does not vary with or take into account the volume or value of referrals or other business generated by the FPP physicians for the teaching hospital.

3. Grandfathering Provision

Recognizing that many parties relied in good faith on the Phase I and Phase II definitions of direct versus indirect compensation arrangements, CMS does not expect the industry to immediately reanalyze and potentially restructure existing business arrangements. Accordingly, CMS clarified that arrangements executed before the Phase III publication date (September 5, 2007), and that satisfied the requirements of the Phase I/II indirect compensation arrangements exception, would not trigger the Stark Law’s referral or billing prohibitions.⁴⁰ This reprieve is of limited value, however. First, it does not extend indefinitely, but terminates at the end of the current term or renewal term of any affected arrangement.⁴¹ Second, it does not necessarily protect arrangements that existed prior to September 5, 2007, but that were not structured to meet all of the require-

ments of the indirect compensation arrangements exception because they did not give rise to an indirect compensation arrangement in the first instance, as defined and interpreted prior to Phase III. Unhelpfully, the status of those arrangements remains decidedly unclear.

The example discussed above illustrates the point. Assume that in 2005, a teaching hospital entered into a five-year mission support agreement with the school and its freestanding, nonprofit FPP. Under the terms of the agreement, the hospital agreed to provide the school \$1 million per year (which the school would then share with the FPP) to develop various oncological educational, clinical, and research programs. Prior to entering the agreement, the parties sought and obtained a written legal analysis that the agreement would not give rise to a financial relationship between the FPP’s physicians and the teaching hospital because the second prong of the indirect compensation arrangement definition was not met—namely, the aggregate compensation received by the FPP’s physicians (in the form of their salary and bonus from the FPP and the university, respectively) did not vary with, or otherwise reflect, the volume or value of referrals or other business generated by the physicians for the teaching hospital.

The parties now ask counsel whether their agreement is protected by the grandfathering provision and, as such, whether they may proceed with the fund transfers contemplated for 2008 and 2009. Logic would suggest that the answer is “yes”; the literal text of Phase III, however, suggests that the answer may be “no”, *unless*, of course, the agreement satisfied the requirements of the indirect compensation arrangements exception prior to September 5, 2007 or the parties are able to rely on the AMC exception. (Of course this entire analysis will now be postponed by one year with respect to AMCs because of CMS’ decision to postpone

the application of the “stand in the shoes” doctrine to AMCs by one year.)

With respect to the indirect compensation arrangements exception, the parties would have to demonstrate, among other things, that the direct compensation arrangement (in the unbroken chain of financial relationships between the referring physicians—via the FPP—and the teaching hospital) that is closest to the referring physicians—via the FPP—provides for the payment of fair market value remuneration for items or services actually rendered.⁴² Because CMS appears to interpret the “stand in the shoes” doctrine to apply to the entire definition of the term “indirect compensation arrangement” (not the first prong only), the closest direct compensation arrangement is the mission support payment. A mission support payment cannot, by definition, reflect a fair market value exchange for services actually rendered. If the payment varies with, or otherwise reflects the volume or value of services between the parties, thus satisfying the second prong of the indirect compensation definition, the parties will have to look to the AMC exception to avoid the referral and billing prohibition.

VI. The AMC Exception Under Phase III

A. ORIGIN OF THE AMC EXCEPTION

The Stark Law does not address the AMC exception; rather, it was developed by CMS pursuant to its statutory authority to adopt additional exceptions by regulation.⁴³ In adopting the AMC exception, CMS noted that the frequent referrals and monetary transfers among components of an AMC create indirect compensation relationships that often will not qualify under the in-office or personal services arrangements exceptions. CMS concluded that a separate exception was necessary to account for “the symbiotic relationship among faculty,

medical centers, and teaching institutions, and the educational and research roles of faculty in these settings.”⁴⁴ The exception, however, contains a long list of criteria that must be met in order for a referral and related reimbursement to be protected. These can be broadly categorized into two groups: the criteria determining the types of entities comprising the AMC; and the criteria determining whether a particular physician’s referrals are protected.

B. THE SCOPE OF THE AMC EXCEPTION AND PHASE III

The first important test when analyzing an arrangement under the AMC exception is whether the services in question are provided by an AMC component. Phase II defines an AMC as consisting of:

- An accredited medical school or accredited academic hospital (i.e., a hospital that sponsors four or more approved medical education programs);
- One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and
- One or more affiliated hospitals in which (i) a *majority* of medical staff members are on faculty, and (ii) a *majority* of all hospital admissions are made by faculty members.⁴⁵

In addition to these three basic criteria for identifying the components of an AMC, the exception requires that their relationship be set forth in one or more written documents that have been adopted by the governing body of each (where the components are separate legal entities).

Phase III leaves virtually unchanged the criteria for determining whether a DHS entity will fit within the AMC umbrella. Specifically, CMS considered and rejected comments seeking to expand the AMC exception by loosening the “majority tests,” thereby making more hospitals eligible to qualify as an affi-

ated hospital.⁴⁶ Instead, CMS tightened the definition of an affiliated hospital by requiring a teaching hospital to either include or exclude all physicians with the same class of privileges when determining whether a majority of its medical staff qualify as faculty physicians.⁴⁷ This change is designed to prevent hospitals from gaming the test by selectively counting courtesy staff who qualify as faculty but excluding those who do not.

The changes CMS proposed to the Stark regulations as part of the Proposed 2008 PFS may ultimately have a significant effect on some AMCs.

Phase III does not clarify the status of other DHS entities controlled by AMC hospitals or FPPs. For example, if a qualified teaching hospital owns a separately licensed entity that is paid for DHS (but is not provider-based), is the entity part of the AMC for purposes of the exception? Similarly, if two or more FPPs own a separate joint venture that is paid for DHS, does the joint venture qualify as part of the AMC? While AMC counsel can develop strategies to increase the likelihood that these DHS entities will come within the AMC umbrella, Phase III leaves these questions largely unanswered.

C. PHASE III CHANGES TO CRITERIA FOR PROTECTING INDIVIDUAL REFERRALS

Assuming that a DHS entity is part of the AMC for purposes of the exception, the next question is whether a particular referral will be protected. In the Phase III preamble, CMS states that

“the regulation is clear that all conditions must be met at the time the referral is made.”⁴⁸ Because there are so many variables in the AMC test, counsel can rarely provide an AMC with unqualified assurance that referrals and related claims will be protected. Phase III does nothing to alleviate this problem for AMCs and, for the reasons discussed below, may exacerbate it.⁴⁹

The only change made by Phase III to the requirements for a protected referral is a re-wording of the compensation test to clarify that, while compensation paid by *each* component must be set in advance, the fair market value test will be applied only to the total compensation paid by *all* components. Thus, for example, if a teaching hospital pays a medical director fee to a faculty physician that supplements his or her employment compensation from the medical school, the teaching hospital could forego applying a fair market value analysis to the medical director fee, so long as the physician’s total compensation from the school and hospital is consistent with fair market value.

D. RETENTION OF THE “SET IN ADVANCE” REQUIREMENT

In the Phase III preamble, CMS rejected a request that it eliminate the “set in advance” requirement for faculty physician compensation arrangements, one of the most intrusive—and difficult to address—characteristics of the AMC exception.⁵⁰ Many medical schools include discretionary compensation plans to recognize significant academic achievement, research, or “team play” characteristics. The “set in advance” requirement contained in the compensation test for the AMC exception largely eliminates this flexibility. To meet the test, the formula must be determined before the beginning of the arrange-

ment and must be sufficiently detailed so as to be objectively verifiable.

In rejecting the request, CMS opined that the purpose of the AMC exception is to protect compensation received by a physician from all components of the AMC, not just the physician's direct employer. Therefore, CMS believes it is appropriate to treat the physician as an independent contractor and apply the "set in advance" requirement applicable to independent contractor arrangements.

But this interpretation ignores another important reason CMS identified in Phase I for adopting the AMC exception, which the agency characterized as recognition of the integrated relationship that exists among entities comprising an AMC, and the numerous financial transactions among related parties that cannot always be defended on a fair market value basis.⁵¹ In particular, these arrangements include mission support and community service arrangements that involve non-fair market value payments from the teaching hospital to the medical school or its FPPs, and that result in indirect compensation arrangements between the teaching hospital and the faculty. The AMC exception protects these arrangements—and nothing in Phase III removes or limits that protection—but the price of the protection can be a considerable loss of flexibility for physician compensation plans. Since the indirect compensation arrangements exception, as vitiated by the "stand in the shoes" rule, may no longer be available to protect these arrangements, AMCs may need to develop new compensation plans that comply with the "set in advance" test of the AMC exception, no matter how incompatible this may be with traditional academic incentive structures. This development is unfortunate, particularly because it seems so unnecessary. Most faculty physicians are compensated as employees, and

both the employment exception and the AMC exception require that total compensation be consistent with fair market value and not be determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Thus, there appears to be no good reason for CMS to impose the additional burden of the "set in advance" test. As it stands, however, with the potential loss of the indirect compensation arrangements exception, some AMCs may have to restructure their compensation plans.

E. ADDITIONAL GUIDANCE IN CMS COMMENTARY ON THE AMC EXCEPTION

Although CMS did not change the AMC exception significantly, the agency did provide some helpful clarifications in the Phase III preamble. It noted that the AMC exception is available for DHS furnished by AMCs that pay physicians for indigent care and community service, provided: (i) all other provisions of the exception are met, and (ii) the money is not from research grants.⁵² CMS also clarified that the definition of an indirect compensation arrangement and the corresponding indirect compensation arrangements exception are potentially applicable to arrangements involving AMCs and physicians. CMS stated that parties may utilize any exception that an arrangement satisfies; it is not necessary to meet the AMC exception if the arrangement meets another exception.⁵³ This clarification would have been reassuring to many AMCs that prior to September 5 relied on the indirect compensation arrangements exception to protect mission support and outreach arrangements; however, as noted above, the application of the new "stand in the shoes" rule to independent FPPs likely eliminates the availability of the indirect compensation arrangements exception to many AMCs.⁵⁴

F. IMPLICATIONS OF 2008 PROPOSED PFS CHANGES

The changes CMS proposed to the Stark regulations as part of the Proposed 2008 PFS may ultimately have a significant effect on some AMCs. CMS released the PFS final rule on November 1, 2007, but chose to defer final action on the Stark provisions.⁵⁵ Among these, however, is a change to the "set in advance" definition that would preclude AMCs from compensating faculty physicians based on a percentage of any measure other than their personally performed services, such as a percentage of departmental savings

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or increased productivity.⁵⁶ This change may not have a significant impact on many AMCs because these types of arrangements can raise other compliance issues under the kick-back and gainsharing laws.

Second, CMS proposed a corollary “stand in the shoes” rule that would apply to affiliated DHS providers.⁵⁷ Specifically, where a DHS entity owns or controls another DHS entity to which a physician refers patients for DHS, the parent DHS entity would stand in the shoes of the subsidiary DHS entity. This proposal may not significantly impact AMCs because the AMC exception often will protect the referrals in any event, but it creates an interesting dynamic for AMCs that have been relying upon the indirect compensation arrangements exception to protect their mission support arrangements. If, for example, a teaching hospital owns or controls a captive physician practice corporation that provides DHS, the effect of the two “stand in the shoes” rules (the Phase III rule and the proposed PFS rule) is remarkable. The medical center will stand down into the shoes of the FPP, while the physician faculty will stand up into the shoes of the same FPP. Presumably then, the Stark Law would no longer apply, as all parties would be standing in the same shoes.

While we can expect CMS to iron-out this anomaly in the forthcoming final rule, it nevertheless points out how difficult it is for CMS ever to finish the Stark regulations. Each change leads to more anomalies, which lead to more changes. The strict liability nature of the Stark Law, coupled with the risk of False Claims Act whistleblower enforcement, eliminates the flexibility to apply common sense to any Stark Law analysis. As a result, CMS is presented with what appears to be a nearly impossible task of developing a rule for every situation.

VII. Conclusion

Phase III defines more compensation arrangements common in AMCs as indirect compensation arrangements, yet eliminates the ability of at least some AMCs to rely on the indirect compensation arrangement exception under 42 C.F.R. § 411.357(p) to protect long-standing financial relationships and referral patterns. The final rule does not, however, offer practical alternatives for compliance through the AMC exception, which applies to a narrow range of relationships and, to be viable, may require significant changes to faculty compensation plans or institutional organization.

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End Notes

- ¹ 72 Fed. Reg. 51011 (Sept. 5, 2007). One week later, CMS proposed further regulatory changes to the self-referral statute in its proposed 2008 physician fee schedule (Proposed 2008 PFS). See 72 Fed. Reg. 38121 (July 12, 2007). As finalized on November 1, 2007, however, the PFS rule does not include any of the proposed changes. CMS-1385-FC, available at www.cms.hhs.gov/physicianfeesched/downloads/CMS-1385-FC.pdf (last accessed Nov. 5, 2007). CMS intends to address those changes in a future final rule without further public comment.
- ² Stark is codified in Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn. Detailed information concerning the statute and its implementing regulations is available at www.cms.hhs.gov/PhysicianSelfReferral/ (last accessed Oct. 29, 2007).
- ³ Pub. L. No. 101-239, § 6204 (1989).
- ⁴ Pub. L. No. 103-66, § 13562 (1993). An incomplete list of HCPCS and CPT codes associated with four of the “designated health services” as defined in the statute is available on the CMS website at www.cms.hhs.gov/PhysicianSelfReferral/

11_List_of_Codes.asp#TopOfPage (last accessed Oct. 29, 2007).

- ⁵ 66 Fed. Reg. 856 (Jan. 4, 2001); 42 C.F.R. pt. 411, subpt. J.
- ⁶ 69 Fed. Reg. 16054 (Mar. 26, 2004).
- ⁷ 72 Fed. Reg. 51011 (Sept. 5, 2007), effective December 4, 2007.
- ⁸ Association of Academic Medical Centers, “Our Members,” at www.aamc.org/about/membership.htm (last accessed Oct. 29, 2007).
- ⁹ According to AAMC, for example, as of 2003, approximately 43% of FPPs were part of a university or medical school, 40% were incorporated separately as nonprofit corporations, 6% operated as professional corporations, and 9% were mixed. Mallon WT, *The Handbook of Academic Medicine: How Medical Schools and Teaching Hospitals Work-Figures and Tables*, AAMC (Jan. 2005).
- ¹⁰ According to AAMC, as of 2003, medical schools received approximately 40–45% of their revenues from hospitals and FPPs. By contrast, tuition and fees accounted for only 2–5% of revenues; 45–48% of revenues were derived from grants, contracts, and state and local appropriations; and 2–6% from endowments and gifts. Mallon WT, *The Handbook of Academic Medicine: How Medical Schools and Teaching Hospitals Work-Figures and Tables*, AAMC (Jan. 2005).
- ¹¹ See, e.g., University HealthSystem Consortium, U.S. Patent 7,003,470 (Feb. 21, 2006) (describing a system and method for tracking and reporting the flow of funds among AMC participants).
- ¹² U.S. Department of Health & Human Services, Office of Inspector General, Advisory Opinions 00-6 (Sept. 29, 2000); 02-11 (Aug. 12, 2002); 05-11 (Aug. 9, 2005).
- ¹³ Arrangements that satisfied the requirements of the indirect compensation arrangements exception as of the publication date of Phase III, i.e., September 5, 2007, are temporarily “grandfathered” under the new regulations.
- ¹⁴ 42 U.S.C. § 1395nn(a)(1)(A). Only referrals to an entity for the furnishing of DHS implicate the Stark Law. By statute, DHS include 11 categories of items and services, including clinical laboratory services, physical therapy services, radiology services (including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services) and inpatient and outpatient hospital services. *Id.* § 1395nn(h)(6).
- ¹⁵ 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b). An entity that submits a claim for reimbursement in violation of the Stark Law must refund any amounts

collected and may (1) pay a civil penalty of up to \$15,000 for each self-referred service and (2) be excluded from participation in federal healthcare programs. *Id.* § 1395nn(g)(2)-(3).

¹⁶ 42 C.F.R. § 411.351 (“entity” definition).

¹⁷ 72 Fed. Reg. at 38186-38187 and 38224.

¹⁸ CMS-1385-FC, at www.cms.hhs.gov/physicianfeesched/downloads/CMS-1385-FC.pdf (last accessed Nov. 5, 2007).

¹⁹ 42 U.S.C. § 1395nn(a)(2); 42 C.F.R. § 411.354(a)(1).

²⁰ 42 C.F.R. § 411.354(a)(1).

²¹ 42 U.S.C. § 1320a-7(b).

²² 42 C.F.R. § 411.357(p).

²³ 42 C.F.R. § 411.354(a)(2).

²⁴ 72 Fed. Reg. 51012 (Sept. 5, 2007).

²⁵ 42 C.F.R. § 411.354(c)(2)(i).

²⁶ Phase III changes the definition of indirect compensation arrangements so that the phrase “otherwise reflects” is replaced with the phrase “takes into account” and thus, on a go forward basis, the definition will require that the referring physician’s aggregated compensation “varies with or takes into account” the volume or value of referrals or other business generated. 72 Fed. Reg. 51087 (Sept. 5, 2007).

²⁷ 42 C.F.R. § 411.354(c)(2)(ii).

²⁸ 42 C.F.R. § 411.354(c)(2)(ii).

²⁹ 42 C.F.R. § 411.354(c)(2)(iii).

³⁰ 72 Fed. Reg. 51087 (Sept. 5, 2007) (42 C.F.R. § 411.354(c)(1)(ii)).

³¹ 72 Fed. Reg. 51087 (Sept. 5, 2007) (42 C.F.R. §§ 411.354(c)(1)(ii)(2)(iv), 411.354(c)(2)(iv)).

³² 72 Fed. Reg. 51087 (Sept. 5, 2007) (42 C.F.R. § 411.354(c)(3)(i)). CMS is silent regarding what happens when the physician organization’s relationship with the DHS entity or some other intervening entity takes the form of an ownership, as opposed to a compensation, relationship.

³³ 72 Fed. Reg. 51083 (Sept. 5, 2007) (42 C.F.R. § 411.351).

³⁴ 72 Fed. Reg. 64161 (Sept. 15, 2007).

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 51029.

³⁸ 72 Fed. Reg. 51087 (Sept. 5, 2007) (42 C.F.R. §§ 411.354(c)(2)(ii) and 411.354(c)(3)(ii)).

³⁹ Importantly, Phase III also provides that the “stand in the shoes” doctrine applies with respect to all of the exceptions set forth in 42 C.F.R. §§ 411.355 and 411.357—a position that may ultimately have drastic implications for the AMC exception.

⁴⁰ 72 Fed. Reg. 51087 (Sept. 5, 2007) (42 C.F.R. § 411.354(c)(3)(ii)).

⁴¹ 72 Fed. Reg. 51028 (Sept. 5, 2007).

⁴² 42 C.F.R. § 411.357(p).

⁴³ 42 U.S.C. § 1395nn(b)(4); 66 Fed. Reg. 856-965 (Jan. 4, 2001).

⁴⁴ 66 Fed. Reg. 856, 916 (Jan. 4, 2001).

⁴⁵ 42 C.F.R. § 411.355(e)(2)(iii), as amended by Phase III. A teaching hospital may include courtesy and volunteer faculty in determining whether it meets the first of the “majority” tests; however, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

⁴⁶ 72 Fed. Reg. 51012, 51037 (Sept. 5, 2007).

⁴⁷ *Id.*, modifying 42 C.F.R. § 411.355(e)(2)(iii).

⁴⁸ 72 Fed. Reg. 51012, 51038 (Sept. 5, 2007).

⁴⁹ 42 C.F.R. § 411.355(e).

⁵⁰ 72 Fed. Reg. 51012, 51037 (Sept. 5, 2007).

⁵¹ 66 Fed. Reg. 856, 916 (Jan. 4, 2001).

⁵² 72 Fed. Reg. 51012, 51036 (Sept. 5, 2007).

⁵³ 72 Fed. Reg. 51012, 51038 (Sept. 5, 2007).

⁵⁴ CMS has stated informally that it will provide additional guidance on the application of the “stand in the shoes” rule to AMCs.

⁵⁵ *See supra* note 1.

⁵⁶ 72 Fed. Reg. 38121, 38184 (July 12, 2007).

⁵⁷ *Id.*

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