

STARK II PHASE III:

A Detailed Section-By-Section Analysis
of the Long-Awaited “Final” Rule

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I. BACKGROUND

The Centers for Medicare & Medicaid Services (“CMS”) has authored a significant new chapter in the long and tortured history of regulations under the physician self-referral statute (“Stark Law”), 42 U.S.C. § 1395nn. The Stark Law prohibits physicians from making referrals to an entity for the furnishing of certain “designated health services” (“DHS”) reimbursable by Medicare, if the physician (or an immediate family member) has a direct or indirect financial relationship with that entity, unless one of many Stark-enumerated “exceptions” exist.

Effective December 4, 2007, “Phase III” of CMS’ final rulemaking under the Stark Law amends existing regulations that were published in the 2001 “Phase I” and 2004 “Phase II” rulemakings, and also introduces new concepts with which physicians, health care organizations, and their counsel must become familiar. To this end, the following presents Crowell & Moring’s in-depth analysis of each provision of the “Phase III” rulemaking. In this publication, CMS has said it “endeavored to simplify the rules ...as well as to reduce any undue burden on the regulated community ...” For the reasons described below, it remains to be seen whether CMS has succeeded in achieving these goals.

It should be understood that this Phase III publication comes on the heels of CMS’ publication of the July, 2007 revisions to the Medicare Physician Fee Schedule (“MPFS Rule”) which it used as a platform for addressing a number of Stark issues through a series of “proposed” regulations and requests for comments on some difficult interpretive issues. Because of what each publication was intended to do, it is important for analytical purposes to, in effect, reverse the order of the two publications: the September-published Phase III establishes final regulations, while the July MPFS publication contemplates additional regulatory changes in the future.

We address each provision in the Phase III rulemaking in the order in which it is presented in the September 5, 2007 Federal Register publication. Where relevant, reference is made to the applicable Code of Federal Regulations section (“CFR”) as well as to the Federal Register page number (“FR”) on which discussion of the subject matter begins.

II. GENERAL COMMENTS

A. Relationship to the Anti-Kickback Statute (FR 51013)

In some respects, the Phase III Final Rule is significant for the changes that CMS chose not to make to the existing Stark regulations. For example, in the Preamble to the Phase III Final Rule, CMS rejects the criticism of “numerous” commenters who objected to existing Stark exceptions that incorporate a condition that the arrangement not “violate the Federal anti-kickback statute,” 42 U.S.C. § 1320a-7b(b). According to CMS, “because parties’ arrangements must not violate

the anti-kickback statute irrespective of whether they satisfy the other requirements of an exception, any additional burden associated with the requirement is minimal.” On a related note, CMS rejected as “not feasible” a suggestion that arrangements which satisfy a Stark exception be deemed compliant with a corresponding safe harbor under the anti-kickback statute.

Although CMS is correct that parties who structure an arrangement to comply with the Stark Law generally must comply with the anti-kickback statute as well, cross-referencing the latter into the requirements of Stark exceptions complicates compliance – perhaps impermissibly. Given the strict liability standard associated with Stark Law compliance, parties should be permitted to structure an arrangement in such a manner that compliance with Stark is clear, absent any analysis as to what other legal obligations (whether the anti-kickback statute, state anti-referral laws, etc.) may also need to be met for purposes of the statutory schemes. In any event, it does not appear that physicians and health care entities can anticipate any change in CMS’ position in this regard, and should always approach Stark Law compliance with the anti-kickback statute in mind.

B. Whither Medicaid?

CMS has promised for years now that it will address the question of how the Stark Law might be applied to Medicaid claims through federal sanction. At present, however, the federal government is left to rely on obligations placed upon state Medicaid programs to enforce Stark-based prohibitions of their own. Until CMS takes up the Medicaid issue directly, only Medicare referrals will remain covered under the Stark Law itself.

III. DEFINITIONS (§ 42 C.F.R. 411.351)

A. Employee (FR 51014)

Although Phase III makes no changes to the definition of the term “employee,” CMS takes the opportunity in the Preamble to caution against arrangements where a group practice “hires” an individual as a part-time employee, but in reality, exercises no control over that individual. While evidence of a W-2 and a written contract are relevant, CMS states that neither is determinative of whether an individual is an “employee” for purposes of the Stark Law. The focus is on the “actual” relationship between the parties.

B. Entity (FR 51014)

There are no changes to the definition of the term “entity” in Phase III, however, CMS noted its intention to “study” and “monitor closely” certain types of arrangements involving physician ownership in entities that derive revenue from DHS entities. Specific reference is made to arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items

and services to entities that furnish DHS, but do not themselves submit claims to Medicare for reimbursement. Such arrangements are particularly problematic, according to CMS, because referrals by physician-owners of these entities, (i.e. a diagnostic equipment leasing company) to the contracting DHS entity (i.e. a hospital) can significantly increase the physician-owned entities profits, creating incentives for overutilization. Upon further study of these types of arrangements, CMS indicated that it would make any changes, whether to the definition of the term “entity” or otherwise, in a separate rule-making. Note that CMS has already proposed these types of changes in the 2008 MPFS Rule issued in July, 2007. There CMS proposes to change the definition of “entity” to also cover the person or entity that either provides the DHS or “causes a claim to be presented for DHS.”

C. Fair Market Value (FR 51015)

In Phase II, CMS created a “safe harbor” for calculating the fair market value of hourly payments for physician services. The safe harbor consisted of two methodologies that, if followed, would deem the hourly payments to be “fair market value.” The first requires that the hourly payment be less than or equal to the average hourly rate for emergency room physician services in the physician market, while the second requires averaging the 50th percentile national compensation level using at least four of six specified salary surveys. Use of the safe harbor is entirely voluntary and CMS emphasized that other methods for establishing fair market value could be used.

Acknowledging the prescriptive and inflexible nature of the safe harbor methodology, the unavailability of certain surveys and the difficulty in obtaining others, as well as the infeasibility of obtaining hourly rates for emergency room physicians at competitor hospitals, CMS eliminated the safe harbor within the definition of “fair market value.” Nonetheless, CMS advised that “reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value.”

CMS also clarified in the Preamble that a fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that “the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative services is fair market value for the administrative work performed.” This clarification is helpful as far as it goes; it does not appear to leave open the possibility of compensating a physician for administrative services at a rate that would offset the fact that he or she is giving up the opportunity to provide presumably more lucrative clinical services during that same time period.

Finally, in confirming that a fair market value hourly rate may be used to calculate an annual salary, CMS states that this can only be done where the multiplier used to calculate the annual salary “accurately reflects the number of

hours *actually worked* by the physician.” This rather narrow guidance leaves open the question of how providers are supposed to prospectively establish annual salaries based on an hourly rate, when *actual* hours worked is an unknown and can only be based upon a reasonable estimation.

D. “Incident to” Services (FR 51016)

1. Calculating Productivity Bonuses and Profit Shares (FR 51022-24)

In order to qualify as a “group practice” under the Stark Law, the practice may not compensate a physician who is a member of the practice, directly or indirectly, based on the volume or value of referrals by the physician. Under the special rule for profit shares and productivity bonuses, however, the Stark Law allows a group practice to pay a physician in the group a share of the overall profits of the group, or a bonus based on services personally performed or service “incident to” such personally performed services, provided that the profit share or bonus is not determined in any manner that is directly related to the volume or value of the physician’s referrals.

In the Phase I rulemaking, CMS expressed its view that physicians can receive compensation directly related to personal productivity and to services “incident to” the physicians personally performed services. In Phase II, CMS reaffirmed this interpretation and revised the regulation to make clear that productivity bonuses can be based directly on “incident to” services. Finally, in Phase III, in response to comments it received to the Phase II revisions, CMS felt that further clarification was warranted and added the following parenthetical to the regulation at § 411.352(i):

(except that the [productivity] bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services “incident to” the physician’s personally performed services).

This clarification eliminates any question regarding the ability of a group practice to take “incident to” services into account when calculating a physician member’s productivity bonus, “even if those ‘incident to’ services are otherwise DHS referrals (for example, physical therapy or outpatient prescription drugs.)” CMS justified this interpretation based on the heightened supervision requirements of the “incident to” billing rules, which would require the referring physician to be onsite and immediately available. Thus, says CMS, the “incident to” DHS would not likely be the primary incentive for the referral.

CMS reversed its Phase II position that overall profit shares could also relate directly to “incident to” services. Upon reflection, CMS concluded that the statute

only allowed for “incident to” services to be included in the context of productivity bonuses.

2. Compliance with Medicare Billing and Payment Requirements (FR 51016)

In the 2001 MPFS Rule, as clarified in the 2003 MPFS Rule, CMS amended the “incident to” billing regulation (§ 410.26) to provide that only those services that do not have their own separate and independently listed benefit category may be billed as “incident to” a physician service (except as otherwise permitted by statute, i.e., certain physical therapy services). Services that have their own benefit category include many diagnostic tests, i.e., x-rays, lab, etc.

This change in the Medicare billing rules impacts the manner in which group practices calculate productivity bonuses. In the Phase III Preamble, CMS clarifies that a physician may not receive a productivity bonus if the bonus is calculated based on diagnostic tests that have a separate benefit category, unless the physician personally performed the test. CMS rejected one commenter’s suggestion that such diagnostic tests be included in the “incident to” definition, so long as the tests are “directly supervised” by the referring physician or a physician in the group practice. CMS concluded that such an approach would lead to conflicting interpretations of “incident to” services and supplies between the Medicare payment rules and the Stark regulations. In furtherance of this point, Phase III deletes § 411.355(a)(3) because it is “redundant and incorrectly suggests that diagnostic tests may be billed as “incident to services.”

Finally, in an effort to conform the self-referral regulations as much as possible to the Medicare billing and payment rules, CMS amends the regulations in two significant ways:

- 1) by revising the definition of “incident to” services at § 411.357 to clarify that the term includes both services and supplies (e.g., drugs) that are furnished “incident to” a physician’s services; and
- 2) adding a new subpart (d) to § 411.350 to specify that these regulations do not alter an individual or entity’s obligations under the reassignment, purchased diagnostic tests, and “incident to” rules.

E. Physician in the Group Practice (FR 51017-51018)

In the commentary related to the “physician in the group practice” definition, CMS reveals its growing concern over the escalation in the number of group practices that demonstrate little nexus between physicians theoretically “in the practice” and the practice itself. To address these concerns CMS makes one textual change and two noteworthy clarifications.

First, CMS modified the definition of “physician in the group practice” to require that an independent contractor physician have a contract directly with the group practice. Noting that group practices receive favorable treatment under Stark, CMS stated that in order to qualify for such treatment, the group practice physicians ought to have a “strong and meaningful nexus” to the group; direct contractual privity provides that nexus. Employees leased from other entities do not so provide.

CMS also clarified – and 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 practices’ facilities. In apparent contrast to its stated position elsewhere in the Preamble regarding consistency between the Medicare payment rules and the self-referral provisions, this interpretation creates an inconsistency between the reassignment rules (which, pursuant to MMA changes in 2003, permit independent contractor physicians to reassign their claims to a group practice for services performed off-premises) and the Stark group practice requirements. CMS explains that although the MMA grants it the “authority” to accept such reassignments, it does not “require” CMS to honor those it believes to be potentially abusive.

The reassignment issue was also the topic of a request for comment in the proposed 2008 MPFS Rule. There CMS expressed concern about the ways in which the general Medicare rule prohibiting markups on the technical component of certain diagnostic tests may be avoided through a) the use of reassignment under contractual arrangements and b) group practices billing for the services of a contracted physician providing services in a Stark-defined “centralized building.” Further rule-making is sure to follow on these issues.

F. Radiology and Certain Other Imaging Services and Radiation Therapy (FR 51018-51019)

CMS made no changes to the definition of the terms “radiology and certain other imaging services” or “radiation therapy services.” CMS did, however, make the following comments (clarification with regard to these services:

- CMS currently excludes from the DHS definition of “radiology and certain other imaging services” those radiology services performed immediately after nonradiology services. Despite clinicians’ assertions that CT scans performed after prostate brachytherapy should be taken several weeks after the procedure, CMS refused to deem such delayed scans as “performed immediately after” nonradiology services. However, CMS hinted that such delayed scans may be considered “necessary and integral” to the brachytherapy itself, and thus may fall within the consultation exclusion from the definition of “referral.”

- CMS refused to exclude from the definition of “referral” ancillary testing necessary and integral to interventional radiology procedures performed as a result of a consultation. It is CMS’ view that interventional radiology is surgical in nature, and that any necessary and integral services would be ancillary to a surgical procedure, rather than to a radiological procedure.
- CMS clarified that the consultation exclusion for radiation oncologists in the definition of “referral” protects only radiation oncology services (1) personally performed or supervised by the radiation oncologist, or (2) supervised by a radiation oncologist in the same group practice. This clarification came in response to a comment that the manner in which the definition of "referral" was amended in the Phase II rule, would allow a radiation oncologist in the consulting radiation oncologist's group practice to supervise the radiation therapy, but not to perform it. CMS confirmed this reading of the regulation.

G. Referral (FR 51019-51021)

In Phase III, CMS made no changes to the definition of the term “referral.” In commentary, CMS restated the Phase I definition of “referral” which excluded services personally performed by a physician who ordered the services, but which specifically included any items or services performed or furnished by anyone else.

In response to commenter inquiries regarding whether there is a “referral” when physicians undertake certain activities, i.e., refilling implantable pumps, or preparing and furnishing antigens (CMS says no referral), CMS discussed the very limited circumstances under which a physician could personally furnish durable medical equipment (“DME”) and supplies. In fact, CMS stated that there are “few if any,” situations in which a referring physician would *personally* furnish DME equipment and supplies to a patient. The reason for this is that in order to do so, the physician would have to be enrolled in Medicare as a DME supplier and meet all of the supplier standards in § 424.57(c). CMS surmises that this is likely not the case for most physicians.

Finally, CMS declined to expand the consultation “carve out” in the definition of referral to include “walk-in” patients (patients who are seen by a physician without having been referred by another physician). CMS’ rationale for not making this change was twofold: 1) such “walk-ins” are not that common, and 2) the fact that a patient “walks-in” to a physician’s office is not determinative with regard to whether or not subsequent referrals for DHS items or services are made by that physician.

IV. GROUP PRACTICE (FR 51021-51024)

See discussion of “Incident To” Services at Section III.D.

V. PROHIBITION ON CERTAIN REFERRALS BY PHYSICIANS AND LIMITATIONS ON BILLING

A. Temporary Non-Compliance (42 C.F.R. § 411.353(f)) (FR 51024-51026)

In Phase II, DHS entities were permitted to submit claims to Medicare and receive payment for DHS services furnished during periods of “temporary non-compliance.” Specifically, if a financial arrangement fell out of a Stark exception and became non-compliant following a 180-day period of compliance, and the non-compliance was beyond the DHS entities’ control, not violative of the anti-kickback statute, and corrected within 90 days, the DHS entity is permitted to submit and be paid for claims during this non-compliant period. In Phase III, CMS makes no revisions to this exception, although several commenter’s questions were addressed in the Preamble.

1. Time Period for Preclusion From Submitting Claims

CMS received comments requesting clarification regarding how long a DHS entity would be precluded from submitting claims for DHS referred by a physician with whom the entity had a non-compliant relationship, where the “temporary non-compliance” exception did not apply. Stating that the Stark Law provides no explicit limitation on the billing and claims submission prohibition, CMS said that it will address this issue in another rule-making, presumably the final 2008 MPFS Rule.

In the proposed 2008 MPFS Rule, CMS requested comments on this issue, referring to it as the “period of disallowance.” CMS questioned whether the “tainted” period should run only from the first day of the tainted arrangement to the date of the correction, or whether referrals *subsequent* to the date of correction should also be prohibited, based on the assumption that such referrals were also incentivized by the payments made under the non-compliant arrangement, and if so, how long the period of disallowance should extend.

2. No Expansion of 90-Day Cure Window

Several commenters suggested implementing a “discovery-based rule” wherein a DHS entity would have a 30 to 90 day window following discovery of the non-compliance in which to cure. Another suggested a “tolling period” for periods of non-compliance where the physician is unable to make referrals to the DHS entity due to a disability, military duty, etc. Still others suggested imposing standards regarding the materiality of the noncompliance or the good faith of the parties.

CMS declined to adopt any of these suggested changes. The discovery-based rule is contrary to the statute, according to CMS, and would also create incentives not to diligently monitor and enforce compliance. The tolling suggestion was dismissed as unnecessary, while the materiality and good faith proposals were deemed to be fraught with enforcement difficulties.

3. Beyond the Control of the DHS Entity

In Phase III, CMS refused to elaborate on the various examples of situations which would be considered “beyond the control of the DHS entity,” citing its exhaustive discussion of this concept in Phase II. CMS further refused to give refuge under this exception to last minute emergency on-call arrangements, stating that the exception could not apply to such arrangements because there would be no pre-existing arrangement that had fallen out of compliance.

With respect to instances of non-compliance caused by third parties, CMS suggested a “case-by-case” approach to determining whether the “beyond the control of the entity” criterion is met. CMS cautioned DHS entities to always maintain adequate and contemporaneous documentation of all financial relationships with referring physicians, including documentation of the terms of each arrangement, whether and how an arrangement fell out of compliance with an exception, steps taken to bring the arrangement into compliance, and other similar information.

B. Minor and Technical Violations

CMS received comments to the Phase II Rule recommending that enforcement officials be allowed to exercise their discretion by declining to pursue minor or technical violations of the Stark Law. Other commenters suggested that a new exception be added allowing physicians to refer for DHS and DHS entities to submit claims in situations where an exception may not apply, but where CMS finds, in its “sole discretion, that there was no abuse.

CMS declined to adopt either suggested approach to enforcement of the Stark Law. Because of the “strict liability” nature of the statute, CMS correctly states that it has no statutory authority to engage in such selective or discretionary enforcement practices.

VI. FINANCIAL RELATIONSHIPS, COMPENSATION AND OWNERSHIP OR INVESTMENT INTEREST (42 C.F.R. § 411.354) (FR 51026)

In Phase III, CMS makes two substantive changes to § 411.354 through revisions to the ownership and investment interest in equipment provisions, and by adding a “stand in the shoes” provision at § 411.354(c).

A. Ownership (FR 51027)

Reconsidering the position it took in the Phase II rulemaking, CMS concludes in Phase III that Congress did not intend for a security interest taken by a physician in equipment sold to a hospital and financed by a loan from the physician to the hospital, to create an ownership or investment interest in the hospital's property. Rather, CMS expressed its current view that such transactions are more appropriately analyzed as compensation arrangements and modified § 411.354(b)(3) accordingly.

This change brings welcome relief to hospitals and physicians hamstrung by CMS' Phase II "ownership" interpretation, due to the inability to bring such security interests then believed to create a "partial" ownership interest in the hospital, within the "whole hospital" exception. It does not appear, however, that the Phase III interpretation inures to the benefit of other types of DHS entities.

B. Compensation (i.e., the "Stand In The Shoes" Provisions) (FR 51027)

In Phase II, CMS solicited comments regarding whether a physician should "stand in the shoes" of his or her group practice for purposes of determining whether he or she has a direct or indirect compensation arrangement with a DHS entity (or, for that matter, no compensation arrangement covered by the Stark Law). In Phase III, CMS revised the compensation rules at 42 C.F.R §§411.354(c)(1)(ii), 411.354(c)(2)(iv) and 411.354(c)(3) to clarify that, when making such a determination, a physician does indeed "stand in the shoes" of his or her "physician organization." CMS defined "physician organization" to include a professional corporation solely owned by the physician, a Stark-compliant group practice, or a "physician practice." Although "physician practice" is not defined, CMS informally indicated that the term is meant to include those group practices that fail to meet all of the regulatory criteria at 42 C.F.R. §411.352.

In the Phase III commentary CMS indicated its concern that parties construe the definition of "indirect compensation arrangement" too narrowly, thus determining that arrangements fall outside the scope of the Stark Law altogether. The "stand in the shoes" provisions seek to "close this unintended loophole."

Under these new rules, a physician will be deemed to have a "direct compensation arrangement" with a DHS entity if the *only* intervening entity between the physician and that DHS entity is the physician's "physician organization," i.e., a physician → physician organization → DHS entity chain of relationships. Accordingly, such arrangements that were previously determined to be either "indirect compensation arrangements" or entirely outside the scope of the Stark Law must now comply with an exception for "direct compensation arrangements" (see Section IX, below, for discussion of such exceptions). When

seeking such an exception, parties must examine the arrangement between the physician organization and the DHS entity as if the physician were a party to the arrangement.

Moreover, a physician will “stand in the shoes” of his or her “physician organization” even if more than one entity intervenes in the chain of relationships between the physician and the DHS entity, e.g., a physician → physician organization → non-DHS entity → DHS entity chain of relationships. However, it is important to keep in mind that such a chain of relationships is covered by the Stark Law only if it satisfies the definitional criteria of “indirect compensation arrangement” at §411.354(c). With respect to such an analysis, particularly whether the physician receives compensation that takes into account the “volume or value of referrals” (see §411.354(c)(2)(ii)), it remains debatable whether one should analyze the physician organization → physician compensation arrangement, or the non-DHS entity → physician organization compensation arrangement as if it were paid to the physician. Regardless, if such a chain of relationships meets the definition of “indirect compensation arrangement,” it must then satisfy the “indirect compensation arrangements exception” (see discussion of 42 C.F.R. §411.357(p), below).

CMS has grandfathered a limited amount of arrangements for purposes of the “stand in the shoes” rules. Specifically, if a physician → physician organization → DHS entity relationship satisfied the “indirect compensation arrangement exception” as of September 5, 2007, the compensation arrangement between the physician organization and the DHS entity need not satisfy an exception for “direct compensation arrangements” until the later of December 4, 2007 or the expiration of the agreement’s current term.

In the proposed 2008 MPFS Rule, CMS proposed that DHS entities stand in the shoes of entities that they own or control. For example, if a DHS entity owns a medical foundation, which maintains a compensation arrangement with a physician, the compensation arrangement must be analyzed as if it were by and between the DHS entity and the physician, and must comply with an exception for “direct compensation arrangements.” Should these rules go into effect, certain 4-party chains of relationships may be collapsible into “direct compensation arrangements.” For example, assume a chain of relationships consists of : DHS entity → DHS-owned entity (e.g., medical foundation) → physician organization → physician. In this example, the DHS entity would stand in the shoes of its medical foundation and (per Phase III) the physician would stand in the shoes of his or her physician organization. Accordingly, the compensation arrangement between the foundation and the physician organization must meet an exception for “direct compensation arrangements,” as if the parties to the arrangement were the DHS entity and the physician.

C. Special Rules on Compensation – Percentage-Based Compensation (42 C.F.R. § 411.354(d)) (FR 510330-31)

The Phase III Rule retains the flexibility for utilizing unit-based and percentage-based compensation formulae that CMS previously sanctioned in Phases I and II. CMS reiterates its cautionary guidance that such formulae will be considered “set in advance” only if fixed at the outset of the arrangement, in sufficient, verifiable detail, and remains unchanged during the course of the agreement.

Contrast this very reasonable interpretation of “set in advance” compensation, however, with CMS’ seemingly conflicting stance in the MPFS Rule. There CMS expresses its concern that, “[d]espite our intent,” percentage-based compensation is being incorporated into equipment and office space leases and other arrangements. As a result, CMS now proposes to clarify that percentage compensation arrangements (1) may only be used for paying for personally performed physician services, and (2) must be based on the revenues directly resulting from the physician services. This limitation would rule out an exclusion for a payment arrangement based, e.g., on the percentage of the savings by a hospital department (that is, “gainsharing” arrangements).

VII. GENERAL EXCEPTIONS TO REFERRAL PROHIBITION RELATED TO OWNERSHIP OR COMPENSATION (§ 411.355)

A. Physician Services (42 C.F.R. § 411.355(a)) (FR 51031-32)

The general Stark prohibitions do not apply to physician services furnished 1) personally by another physician in the referring physician’s group practice or 2) under the supervision of another physician “in the referring physician’s group practice” (including an “independent contractor” who, while qualifying as a “physician in the group,” is not a group “member”).

No substantive changes were made to this exception in Phase III. CMS has, however, made a clarification by deleting § 411.355(a)(3) to make certain that diagnostic tests are not included in those “incident to” services that may come under the coverage of “physician services.” To be clear, these tests cannot qualify under this exception. (See discussion of “incident to” services at Section III.D.)

CMS also notes that it intends to further study the question of contracted physicians performing laboratory services in off-site “pod labs.” The 2008 MPFS Rule already proposes that such arrangements not qualify for “mark ups” unless the physician is a full-time employee.

B. In-Office Ancillary Services (42 C.F.R. § 411.355(b)) (FR 51032-35)

The in-office ancillary services exception (“IOAE”) is an important and useful exception on which properly-formed group practices may rely to except virtually all DHS referrals. Although the ways in which the IOAE may be met were liberalized in Phase II, CMS is now concerned the exception may have gotten out of hand. One commenter in fact suggested to CMS that the IOAE is the “exception that swallows the rule.” Indeed, in the July MPFS publication, CMS acknowledged that changes may need to be made to the IOAE, and it solicited comments as to whether the exception ought to be narrowed, and/or whether some DHS ought not remain covered by the exception.

Despite these concerns, CMS makes no substantive changes to the IOAE in Phase III. The agency notes again, however, that additional rulemaking may be forthcoming. Phase, III does, however, include some clarifying commentary on the scope and purpose of the IOAE. Among CMS’ key responses to comments on the exception:

- CMS makes clear that care must be taken when DHS space is “shared” by two groups in the “same building.” Each group must control the space, equipment, and staffing at the time it intends to provide its group DHS. CMS notes that “block leases” are probably necessitated. “Per use” fee arrangements will likely not satisfy the supervision requirement.
- With regard to the use of the “centralized building” approach to meeting the IOAE, CMS cautions that part-time, shared space, “condominium” arrangements are “easily subject to abuse.” Any arrangement in which the group practice is not in full control of the centralized building premises 24/7 will simply not meet the exception.
- CMS signaled its intent to examine whether specific DHS ought not be protected by the exception due to potential abuses, identifying by name those involving “in-office pathology labs” and “sophisticated imaging equipment” as susceptible to further inspection.

C. Services Furnished by an Organization for its Contractors or Subcontractors to Enrollees (42 C.F.R. § 411.355(c)) (FR 51035)

This exception covers services provided pursuant to certain Medicare and Medicaid managed care contracts. No changes were made to this exception in Phase III.

D. Reserved

E. Academic Medical Centers (42 C.F.R. § 411.355(e)) (FR 51036-38)

The academic medical center (“AMC”) exception was broadened in the proposed Phase II rule to permit more academic-focused entities to qualify for the exception. CMS also proposed to loosen the “formal writing” requirements describing the AMC relationships, and added a “safe harbor” deeming any physician who spends 20 percent of his time or eight hours per week providing academic or clinical teaching services as providing “substantial” clinical teaching or academic services for purposes of the exception.

In Phase III, these Phase II changes are adopted with very minor clarifications. These clarifications relate to how it is determined whether a “majority of the medical staff” consists of “faculty members,” simply requiring that whatever medical staff category is used in the numerators also be used in the denominators. In addition, CMS has revised the exception’s language to make clear that the total compensation for each academic medical center component to a faculty physician must be set in advance and not based upon the volume or value of referrals. Finally, CMS reminds that the AMC exception is designed to supplement, not replace, other exceptions.

Of more interest and, indeed, some controversy, one commenter asked CMS how the “indirect compensation arrangement” exception might apply in the AMC setting. The example given was one where a hospital component of an AMC was a separate entity from the university that operated a faculty practice plan in connection with the university’s medical school. The commenter described a situation where the hospital paid the university for the physician’s services, and the physicians were university employees. Thus the compensation chain went hospital→ university →faculty practice plan →physician. The question posed was whether this was an indirect compensation arrangement or an “uncovered” arrangement, given that the physicians were salaried employees of the plan.

CMS’ response was telling: “with respect to the situation described by the commenter, we have revised § 411.354 to clarify the application of the indirect compensation definition...and exception.” True enough, but what CMS does not state is that when one considers that definition, the arrangement described remains uncovered by the Stark Law. (See “indirect compensation arrangement” analysis at Section IX.P.).

Also ignored in the AMC commentary to Phase III, but now emerging in post-publication discourse, is the fact that the new “stand in the shoes” doctrine (coupled with the 2008 MPFS proposals for collapsing the DHS entity side of the

compensation chain) may wreak havoc upon routine AMC compensation formats, unnecessarily requiring revisions to these models. At this writing, CMS has recognized that the “stand in the shoes” concept, when applied in the AMC situation, will lead to unintended results. We therefore expect revisions to the “stand in the shoes” approach – perhaps with specific reference to its application to “faculty practice plans” – in the very near future.

F. Implants furnished in Ambulatory Surgery Centers (42 C.F.R. § 411.355(g)) (FR 51038)

This exception permits physician owners of ambulatory surgery centers to order and perform surgeries that include the implantation of DME or other devices. Phase III makes clear that the exception only applies if the ASC, not the physician, submits the claim.

G. EPO and Other Dialysis-Related Drugs Furnished In or By an End-Stage Renal Dialysis Facility (42 C.F.R. § 411.355(g)) (FR 51038)

This exception covers referrals for EPO and other dialysis-related outpatient drugs used in end-stage renal dialysis facilities. No changes were made in this exception.

H. Preventive Screening Tests, Immunizations and Vaccines (42 C.F.R. § 411.355(h)) (FR 51039)

This exception covers referrals for certain preventive screening tests, immunizations, and vaccines furnished under circumstances that do not pose risks of abuse. (These services do not include mammography or pap smears.) No changes were made to this exception.

I. Eyeglasses and Contact Lenses Following Cataract Surgery (42 C.F.R. § 411.355(i)) (FR 51039)

This exception covers the ordering of the supplies describe in its title. No changes were made to this exception.

J. Intra-Family Rural Referrals (42 C.F.R. § 411.355(j)) (FR 51039-41)

This exception covers referrals made by a referring physician to his or her immediate family member to a DHS entity in which a family member has a financial relationship, provided that the patient resides in a rural area and there would otherwise be access difficulties for the patient (e.g., the DHS is not available within 25 miles of the patient’s home).

Phase III adds an alternative test for determining whether DHS is otherwise “unavailable” to the patient. In addition to the 25-mile test, a physician may refer a patient to an immediate family member if the DHS in question cannot otherwise be provided within 45 minutes of the patient’s home.

VIII. EXCEPTIONS TO THE REFERRAL PROHIBITION RELATED TO OWNERSHIP OR INVESTMENT INTERESTS (§ 411.356)

A. Publicly-Traded Securities and Mutual Funds (42 C.F.R. § 411.356(a)) (FR 51041)

This exception permits physicians (or family members) to acquire stock in public companies that own DHS entities if the transaction does not favor physicians over other purchasers. No changes were made to this exception in Phase III.

B. Hospitals Located in Puerto Rico (42 C.F.R. § 411.356(c)(1)) (FR 51041)

Under this exception ownership and investment interests in hospitals located in Puerto Rico are not covered by the statute. No changes to this exception were made in Phase III.

C. Rural Provider (42 C.F.R. § 411.256(c)(2)) (FR 51041-42)

This exception covers ownership investment interests in facilities that furnish DHS to a “rural area.” The test for qualifying as a “rural provider” is whether at least 75% of the entity’s total DHS is provided to patients living within a rural area. (The DHS entity itself need not be located in a rural area.) Phase II adopted as a final rule the definition that a “rural area” is one “not defined as a Metropolitan Statistical Area.” Phase III makes no substantive changes to this exception.

Commentary in the Phase III publication provides clarification that the exception covers only a physician’s “ownership or investment interest” in the rural provider. Therefore, if a compensation arrangement between the physician and a DHS entity also exists, that arrangement must meet an exception for DHS referrals to be permitted.

D. Ownership Interest in a Whole Hospital (42 C.F.R. § 411.356(c)(3)) (FR 51042-43)

This exception covers physician (or family member) ownership interests in a hospital entity. Although this exception remains at this writing the subject of pending legislation which could affect its future – particularly with respect to specialty hospitals (See Section XI) – Phase III makes no changes to this exception.

CMS observed in its commentary that the exception does not protect referrals for services provided by a hospital's affiliates or subsidiaries.

IX. EXCEPTIONS RELATED TO COMPENSATION ARRANGEMENTS

A. Rental of Office Space (42 C.F.R. § 411.357(a)) (FR 51043)

In Phase II regulatory changes, CMS permitted (1) the termination of space leases “without cause,” to the extent the parties do not enter into a “new agreement” within the first year of the original term; (2) holdover tenancies of no more than six months; (3) subleases; and (4) “per-click” lease arrangements. In Phase III, CMS made no changes to the regulatory text.

In Phase III, CMS clarified, however, that, because rental charges for office space must be “set in advance,” rental rates must not be changed during *any* period of the lease's effectiveness. Similarly, changes to terms “material to” the rental rate (e.g., square footage) may not be changed if doing so would cause the rental rate to be inconsistent with “fair market value” or relate to the “volume or value” of one party's referrals. Further, changes to rental rates and such other “material” terms may only be effectuated by actually terminating the lease and executing a new one; the customary method of amending a lease would violate the “set in advance” rule.

CMS also indicated that a lessee may store and use limited equipment (such as scales and fluid drawing equipment) in common areas, even if the lessee pays only a prorated rental amount for such areas. However, full exam rooms may not be considered “common areas.”

CMS settled potential confusion by stating that parties may terminate an office space lease within the first year of the original term and enter into a new lease for *different* space; the parties are merely prohibited from executing a new lease for the *same* space during that first year.

CMS clarified that, should a lessor make an improvement that would not be used by a subsequent tenant, the lessor may not allocate to the tenant the cost of that improvement over the life of the improvement, but rather must allocate it over the life of the lease.

Finally, CMS clarified that a lessor may impose a holdover premium, to the extent it is established in the terms of the lease, but holdovers – including eviction grace periods – must not exceed six months.

Retracting its previous permissive stance in the 2008 MPFS Rule, CMS has proposed to prohibit “per-click” office space leases wherein a DHS entity leases space to a physician, and the physician's “per-click” payments are for the use of the DHS entity's space in providing services to patients sent to the physician by the

DHS entity. In addition, albeit not a proposed change to this exception, the MPFS Rule's proposal to sharply proscribe the use of percentage-based compensation may impact some office space leases.

B. Rental of Equipment (42 C.F.R. § 411.357(b)) (FR 51045)

The Phase II regulatory changes made to the exception for rentals of office space were also made to this exception. In Phase III, CMS made no changes to the regulatory text. CMS indicated that the commentary pertinent to the exception for rentals of office space applied equally to this exception. Finally, CMS' proposal in the 2008 MPFS Rule to prohibit certain "per-click" lease arrangements (as discussed above) extends equally to office space and equipment leases. Similarly, the PFS Rule's proposal to sharply proscribe the use of percentage-based compensation may impact some equipment leases.

C. *Bona Fide* Employment Relationships (42 C.F.R. § 411.357(c)) (FR 51045)

This exception permits payments made by an employer to a *bona fide* employee physician (or immediate family member) if certain conditions are met. CMS did not receive any comments related to this exception, and CMS did not make any comments or changes of its own.

D. Personal Service Arrangements (42 C.F.R. § 411.357(d)) (FR 51045)

In Phase II regulatory changes, CMS permitted the termination of personal services arrangements "without cause," to the extent the parties do not enter into "the same or substantially the same" agreement within the first year of the original term. In Phase III, CMS made minor changes to the regulatory text of this exception, permitting a "holdover" personal services arrangement in the same manner that a holdover lease is permitted. In other words, services provided after the expiration of a personal services arrangement that met the requirements of this exception will continue to be excepted, for a period not to exceed six (6) months. CMS also made a technical change to the definition of "physician incentive plan," to reference the new definition of "downstream contractor."

CMS also made a technical change to this exception's definition of "physician incentive plan," i.e., to refer to the new definition of "downstream contractor" at 411.351. As opposed to the exception's previous, vexatious use of both "downstream contractor" and "downstream subcontractor," "downstream contractor" is now defined to encompass the Federal health care program anti-kickback statute's regulatory definitions of both "first tier contractor" and "downstream contractor." Under those definitions, a "first tier contractor" means an "individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services," and a "downstream contractor" means "an individual

or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor." Accordingly, physicians and physician practices that qualify under such definitions are able to participate in physician incentive plans excepted under 411.357(d)(2).

In Phase III, similar to its commentary pertaining to the exception for rentals of office space, CMS clarified that, because payments for personal services must be "set in advance," the payment rate and methodology must not be changed during *any* period of the agreement's effectiveness. Similarly, changes to terms "material to" the payment rate (e.g., scope of services) may not be changed if doing so would cause the payment rate to be inconsistent with "fair market value" or relate to the "volume or value" of one party's referrals. Further, changes to payment rates, methodologies, and other "material" terms may only be effectuated by actually terminating the agreement and executing a new one; the customary method of amending an agreement would violate the "set in advance" rule.

Finally, although not a proposed change to this exception, the 2008 MPFS Rule's proposal to sharply proscribe the use of percentage-based compensation would likely impact many personal service arrangements, and would appear to directly prohibit gainsharing arrangements.

E. Physician Recruitment (42 C.F.R. § 411.357(e)) (FR 51047-51054)

The physician recruitment exception has occupied a great deal of CMS' attention in past Stark publications. In Phase II, for example, significant modifications were made to the exception, including the following changes.

To qualify for the exception, the recruited physician:

- Must relocate his practice, not his residence
- Must be new to the hospital's medical staff
- Must relocate to within the recruiting hospital's service area (the lowest number of contiguous zip codes from which the hospital draws 75% of its patients)
- Must relocate at least 25 miles or establish that 75% of his revenues come from new patients.

The Phase II Rule also provided that residents and physicians in practice less than a year may qualify for the exception, and that federally-qualified health centers – as well as hospitals – may make recruitment payments. Finally, the rule established conditions through which payments could be made to physicians

through “host” group practices. These rules were intended to insure that no benefit would flow to the group through their intermediary role in the recruitment arrangement.

Following the publication of Phase II, CMS received numerous comments concerning its changes to the recruitment exception. Many commenters were highly critical of the constraints placed upon the recruitment compensation flow when a group was involved, arguing that the constraints imposed by CMS significantly dampened a hospital’s ability to recruit clearly needed physicians. As a result of this critical feedback, CMS has made additional adjustments to the exception in Phase III. These adjustments should provide breathing room for hospitals and group practices to craft fair yet appropriate recruitment packages when a new physician is deemed needed in a particular area. Among these adjustments are the following:

- Rural health clinics may now utilize the exception
- The geographic area “served by the hospital” may now be comprised of all the contiguous zip codes from which the hospital draws its inpatients when the hospital draws fewer than 75% of its patients from contiguous zip codes (providing more flexibility in drawing the geographic service area).
- Rural hospitals may determine their “geographic area” using an alternative test that encompasses the lowest number of contiguous (or in some areas, non-contiguous) zip codes from which the hospital draws at least 90% of its patients.
- The guarantee paid to physicians replacing a deceased, relocated, or retired physician may now include additional costs to the group calculated on a per capita basis (not to exceed 20%) of the group’s aggregate costs, rather than simply the “incremental costs” attributed to the recruited physician.
- To qualify for recruitment, a physician must both a) move into the hospital’s geographic area and b) move 25 miles (or establish a new medical practice where 75% of the patients are new).
- Certain physicians may qualify for the relocation requirement if they have served for two (2) years or more in certain government employment positions.

These changes to the rule will loosen current constraints on recruiting efforts of hospitals and “host” group practices. Further, CMS’ commentary on the recruitment exception provides additional helpful interpretations. Notably, CMS acknowledges now that its prior interpretation of “restrictions on practice” (which

could not be placed on a recruited physician) was too strict. While CMS reaffirms its view that recruitment agreements cannot prohibit a physician from becoming a member of another medical staff or referring patients to another hospital, it now concedes that restrictions such as a “non compete” do not fall in the same category. As a result, recruitment agreements may now properly include non-compete clauses (so long as the clause is consistent with applicable state law). Other “restrictions” which now may clearly be part of a recruitment agreement include:

- Restrictions on moonlighting
- Restrictions on soliciting patients or employees
- Requirements to treat Medicaid or indigent patients
- Requirements that physicians pay losses his/her practice absorbs in excess of the hospital’s payments
- Establishing liquidated damages in the event the physician relocates before his agreement has expired.

While these types of contractual clauses may appear more onerous for recruited physicians, it appears that CMS has appropriately responded to comments that strongly asserted that recruitment efforts had been unduly encumbered under prior regulation and interpretation.

Turning to the “host” group practices, aside from permitting greater flexibility in the “incremental cost” allocation formula for the recruited physician in certain situations, CMS observed that it was appropriate for a hospital to require a group practice to guarantee repayment of a recruited physician’s loan. The agency warned, however, that forgiveness of the obligation could lead to fraud and abuse violations. CMS also clarified that “income guarantees” may be based upon revenue, gross income, or net income.

F. Isolated Transactions (42 C.F.R. § 411.357(f)) (FR 51054)

In Phase II regulatory changes, CMS clarified that (1) parties subject to an isolated transaction must not have any other dealings for six months, save arrangements that meet other Stark exceptions; (2) installment payments related to an isolated transaction may meet the exception, to the extent they are subject to a mechanism that ensures payment in the event of default; and (3) commercially reasonable post-closing adjustments made within six months are permissible. In Phase III, CMS made no changes to the regulatory text.

Although CMS declined to extend the period during which post-closing adjustments may be made, it stated that claims based on breach of warranty are not considered post-closing adjustments or new transactions. CMS considers such

claims to be part of the original transaction and, regardless of when they are made, will not consider them to jeopardize compliance with this exception.

G. Remuneration Unrelated to DHS (42 C.F.R. § 411.357(g)) (FR 51056)

In Phase II, CMS clarified that remuneration must be *wholly* unrelated to the provision of DHS for this exception to apply. In Phase III, CMS made no changes to the regulatory text. In commentary, however, CMS stated that waiving physicians' entry fee into a DHS entity's charity golf tournament would constitute a targeted benefit, if non-physicians had to pay to enter the tournament. CMS also clarified that if a hospital provides remuneration to a physician and the hospital does not and could not reasonably be expected to know whether the item, service, or cost could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles, CMS would consider the remuneration to be unrelated to the furnishing of DHS.

H. Group Practice Arrangements with a Hospital (42 C.F.R. § 411.357(h)) (FR 51056)

This exception applies to certain arrangements between a group practice and a hospital whereby the group furnishes DHS that are billed by the hospital. CMS did not receive any comments related to this exception, and CMS did not make any comments or revisions of its own.

I. Payments by a Physician (42 C.F.R. § 411.357(i)) (FR 51056)

In Phase II, CMS clarified that this exception may not apply if another potentially applicable exception is available. In Phase III, CMS made no changes to the regulatory text. As a result of the expansion of this exception for fair market value compensation, i.e., to except payments made both *by* and *to* physicians (see further discussion of 42 C.F.R. §411.357(l), below), CMS clarified in commentary that this exception is now even more unattainable. In other words, if a hospital leases equipment to a physician for a term of less than one year, the parties must now rely on the exception for fair market value compensation, and cannot rely on this exception.

J. Charitable Donations by a Physician (42 C.F.R. § 411.357(j)) (FR 51057)

In Phase II, CMS established this exception. In Phase III, CMS changed the regulatory text to clarify that a charitable donation may not be "solicited" or "offered" in any manner that reflects the volume or value of referrals. CMS indicated that it made the regulatory change to appease donees concerned that their acceptance of a donation would be unexcepted, even if they had no knowledge that

the donor made the donation in consideration of referral volume. Despite this commentary, it is unclear whether the regulatory text accomplishes CMS' intent.

K. Nonmonetary Compensation (42 C.F.R. § 411.357(k)) (FR 51058)

In Phase II, CMS added significant conditions and clarity to this exception, which had previously excepted nonmonetary compensation provided to physicians up to \$300 per year. In Phase III, CMS made two further significant changes to the regulatory text. First, the exception now allows physicians to repay excess nonmonetary compensation, to the extent (a) the excess compensation was made inadvertently, (b) the excess compensation does not exceed 50% of the limit, (c) the physician repays the excess within the same calendar year or within 180 days, and (d) the DHS entity and the physician at issue do not rely upon this provision more than once every three years. Second, DHS entities may now – without regard to the annual, monetary limits imposed by the exception – provide one annual, local medical staff appreciation function for the entire medical staff, no strings attached.

CMS stated that its goal in making these revisions was to protect DHS entities and physicians from “disastrous and uncertain” results related to inadvertent making (or accepting) of non-monetary compensation in excess of the limit, and therefore that claims submissions made during the period that a physician retains the excess nonmonetary compensation will *not* violate the Stark Law, as long as the repayment is made in accordance with the exception’s requirements. However, CMS stated that it would be “prudent” for the DHS entity to delay claims submission until after the physician repays the excess. With respect to the permitted medical staff function, CMS stated that gifts and gratuities provided in connection with the event must still achieve the exception.

In addition, CMS clarified that the monetary limit (\$327 for 2007) applies to each DHS entity within a health system, and not to the health system itself. CMS also stated that DHS entities should implement tracking and valuation mechanisms related to the provision of nonmonetary compensation, and should not provide benefits to physicians about which they are unaware or for which they are unable to account.

Although not specific to this exception, CMS solicited comments in the proposed 2008 MPFS Rule on how it should prescribe periods of disallowance in instances where it is more difficult to ascertain the start and end dates of non-compliance with a Stark exception. CMS specifically inquired as to whether it would be appropriate to “disqualify” parties from using statutory or regulatory exceptions that they otherwise would have met. For instance, if an entity provides non-monetary compensation to a physician in the amount of \$900, should the parties be disqualified from utilizing the pertinent exception for two additional years, i.e., until the parties “spend down” three years’ worth of \$300 payments?

Should such a “spend down” feature be adopted, it is unclear if CMS would then view as permissible a hospital’s donation to a physician of a \$900 piece of equipment, if no donations were made to that physician in the subsequent two-year period.

L. Fair Market Value Compensation (42 C.F.R. § 411.357(l)) (FR 51059)

Phase II made no substantive changes to this exception. In Phase III, CMS made one substantive and one clarifying change to the regulatory text. The exception, which previously applied only to compensation paid from a DHS entity to a physician, now also applies to compensation paid from a physician to a DHS entity. In addition, CMS clarified that this exception is inapplicable to leases for office space; such leases must comply with the exception for rentals of office space.

As a result of the expansion of this exception, i.e., to except payments made both *by* and *to* physicians, CMS made the exception for “payments by a physician” (42 C.F.R. §411.357(i)) even more unattainable. In other words, if a hospital leases equipment to a physician for a term of less than one year, the parties must now rely on this exception to comply with the Stark Law, and cannot rely on the more flexible exception for payments by a physician. CMS also clarified that a hospital’s expenses in recruiting a physician cannot qualify for this exception.

M. Medical Staff Incidental Benefits (42 C.F.R. § 411.357(m)) (FR 51060)

In Phase II, CMS (1) made efforts to distinguish this exception from the exception for non-monetary compensation, (2) expanded the exception to apply to incidental benefits provided not only by hospitals, but also by any entity with a *bona fide* medical staff, and (3) tied the annual dollar limit to the CPI-U. In Phase III, CMS made no changes to the regulatory text.

In response to comments, CMS made clear that a device that is used to access patients or personnel qualifies for this exception as long as the device can only be used to access patients and personnel who are on the hospital’s campus; if a physician can use the device to contact home-bound patients or colleagues in-transit, for example, the provision of the device must qualify for another exception. CMS also indicated that certain physician referral services operated by hospitals may qualify for this exception.

N. Risk-sharing Arrangements (42 C.F.R. § 411.357(n)) (FR 51060)

This exception applies to compensation (i.e., withholds, bonuses, risk pools) between a managed care organization and a physician for services provided to

enrollees of a health plan. CMS did not receive any comments related to this exception, and CMS did not make any comments or revisions of its own.

O. Compliance Training (42 C.F.R. § 411.357(o)) (FR 51070)

In Phase II, CMS amended this exception to allow hospitals to provide certain compliance training to physicians, but to exclude programs for which CME credit is available. In Phase III, CMS revised the exception to permit compliance programs for which CME credit is available, but only to the extent compliance training is the “primary purpose” of the program. CMS clarified that CME programs that merely contain a compliance training component (e.g., a cardiology seminar with one session on fraud and abuse compliance) will not qualify for the exception; the entirety of the seminar must have compliance as its primary purpose. CMS also clarified that hospitals may provide online compliance training, but physicians must access the training while within the hospital’s local community or service area.

P. Indirect Compensation Arrangements (42 C.F.R. § 411.357(p)) (FR 51043)

In Phase II, CMS made no changes to this exception. Similarly, in Phase III, CMS made no changes to the regulatory text regarding indirect compensation. CMS confirmed in the Phase III Preamble, however, that any chain of relationships between a physician and a DHS entity that meets the definition of an “indirect compensation arrangement” must satisfy this exception; no other exception is available. Accordingly, if an indirect compensation arrangement is created after a physician “stands in the shoes” of his or her physician organization (see discussion in Section VI.B., above), that arrangement *must* satisfy this exception. However, with respect to such an arrangement and when analyzing whether the compensation “received” by the physician takes into account the volume or value of the physician’s referrals to the DHS entity, it remains a debatable point whether one must (a) examine the compensation paid by the physician organization to the physician, or (b) examine the compensation paid to the physician organization, as if it were paid to the physician vis-à-vis the “stand in the shoes” provisions. Further guidance from CMS on this point may be forthcoming.

In addition, CMS clarified that if a physician is paid on a percentage-of-collections basis, that compensation arrangement may endanger the parties’ compliance with this exception. CMS indicated that it will look to *actual collections* to determine whether the compensation “received” by the physician results in fair market value. Accordingly, surprisingly low or high collection rates may result in an unexcepted arrangement.

Q. Referral Services (42 C.F.R. § 411.357(q)) (FR 51063)

In Phase II, CMS used its regulatory authority to create this exception. In Phase III, CMS made no changes to the regulatory text. CMS did not receive any comments related to this exception, and CMS did not make any comments or revisions of its own.

R. Obstetrical Malpractice Insurance Subsidies (42 C.F.R. § 411.357(r)) (FR 51063)

In Phase II, CMS used its regulatory authority to create this exception, permitting any obstetrical malpractice insurance subsidy that meets all the criteria contained in the Federal health care program anti-kickback statute's regulatory safe harbor for such subsidies (see 42 C.F.R. §1001.952(o)). In Phase III, CMS made no changes to the regulatory text. Noting that several exceptions may be utilized to shelter insurance subsidies, CMS declined to expand this exception to permit subsidies by all hospitals and for all specialties. In contrast, in the proposed MPFS Rule, CMS indicated a willingness to expand the scope of this exception, requesting public comment on how to divorce this exception from the anti-kickback statute safe harbor and accommodate more flexible "locational" requirements, e.g., whether the subsidizing entity, the physician, and the patients must each be located within a HPSA or an MUA, or whether the patients must be part of an MUP.

S. Professional Courtesy (42 C.F.R. § 411.357(s)) (FR 51064)

In Phase II, CMS created this exception to allow for the provision of professional courtesy to a physician or his or her immediate family members. In Phase III, CMS made one substantive change to the regulatory text, deleting the requirement that an entity notify an insurer when the provided courtesy involves the whole or partial reduction of any coinsurance obligation. CMS also modified the exception to make clear that (1) only hospitals and other providers with formal medical staffs may utilize the exception; and (2) entities *must* have a written policy that is approved by the entity's governing body. CMS clarified that suppliers such as laboratories and DME companies cannot utilize this exception for any professional courtesy provided. In addition, CMS stated that, for purposes of this exception, CMS will consider a group practice or other physician practice to be an entity with a "formal medical staff," and thus an entity that could utilize the exception.

T. Retention Payments in Underserved Areas (42 C.F.R. § 411.357(t)) (FR 51065)

In Phase II, CMS created this exception to permit retention payments made to a physician by a hospital or FQHC located in a HPSA. The exception contained several conditions, including that the physician have a *bona fide* written recruitment offer from another hospital or FQHC that would require the physician

to move his or her practice at least 25 miles *and* outside of the original hospital's or FQHC's geographic service area. In Phase III, CMS made several modifications to the regulatory text, making this exception more flexible:

(1) a retention payment is now permitted in the absence of a written offer, as long as the physician certifies in writing that, among other things, he or she has a *bona fide* opportunity for future employment (from an entity listed in (4), below), and as long as the retention payment does not exceed the lower of:

(a) 25% of the physician's current annual income; or

(b) the reasonable costs of recruiting another physician to replace the physician;

(2) rural health clinics are now capable of making an excepted retention payment;

(3) a retention payment is now permitted when it is made to a physician whose current medical practice is in a rural area, a HPSA, an area of demonstrated need (as determined in an advisory opinion), or where at least 75% of the physician's patients either reside in an MUA or are members of an MUP; and

(4) entities can now make retention payments to match offers made not only by hospitals, but also by academic medical centers and physician organizations (as defined by 42 C.F.R. §411.351).

CMS stated that, in calculating the reasonable amount of an excepted retention payment, hospitals, rural health clinics, and FQHCs may take into account the original physician's experience, training, and length of service in the area. In addition, CMS stated that, when calculating the "costs of a replacement," both direct and indirect costs can be included. CMS also clarified that, unlike the exception for physician recruitment, this exception does not protect retention payments made to or through a group practice.

U. Community-Wide Health Information Systems (42 C.F.R. § 411.357(u)) (FR 51068)

In Phase II, CMS used its regulatory authority to create this exception. In Phase III, CMS made no changes to the regulatory text. CMS indicated that it received several comments seeking clarity regarding the scope of this exception. However, CMS stated that it would not make any further revisions or issue any further guidance concerning this exception until it observes how market participants accept the new and similar regulatory exceptions for donations of

electronic prescribing and electronic health records technology items and services (see 42 C.F.R. §§ 411.357(v) and (w)).

X. REPORTING OBLIGATIONS

The Stark law and corresponding regulations impose certain reporting requirements on parties providing covered items or services for which payment may be made under Medicare. 42 U.S.C. § 1395(f); 42 C.F.R. § 411.361. In the Phase III Final Rule, CMS has amended its regulations to account for the ongoing implementation of the National Provider Identifier (NPI). Although CMS did not implement further substantive changes, the Preamble includes helpful information for reporting parties. For example, CMS clarifies that much of the reported information that it receives will be exempt from public disclosure under the Freedom of Information Act (FOIA) and prohibited from disclosure by the Trade Secrets Act. CMS has refused, however, to state categorically that all reported information would be protected from disclosure under FOIA or the Trade Secrets Act.

Some who commented on the earlier Phase I and Phase II rulemakings raised concerns that the existing reporting obligations are “staggering” and “unnecessar[il]y burden[some].” CMS rejects these commenters’ suggestions, expressing its concern that any failure to maintain or report the required information would impede the government’s ability to assess the compliance of a particular arrangement. CMS indicates, however, that it will use its discretion with regard to reporting deadlines and will extend such deadlines beyond 30 days when appropriate.

CMS’ position on reporting requirements comes as little surprise. As a threshold matter, these requirements are to a large degree mandated by federal statute. Moreover, notwithstanding the burdens that potential reporting obligations may impose on parties subject to Stark, CMS was unlikely to sacrifice its own ability to investigate and audit compliance with Stark and related laws.

XI. MISCELLANEOUS MATTERS -- Specialty Hospital Moratorium

Although the 18-month moratorium on Stark exceptions for physician ownership and investment in specialty hospitals implemented under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) ended on June 7, 2005, CMS provides noteworthy information in the Phase III rulemaking related to specialty hospitals. In particular, CMS indicates that it is exploring changes to the Medicare enrollment form for hospitals (CMS-855A) to capture information regarding whether an applicant hospital is, or is projected to be, a specialty hospital. Such changes may include defining the term, “primarily engaged,” to assess whether a hospital is “primarily engaged” in the care and treatment of patients with a cardiac condition, patients with an orthopedic condition, or patients receiving a surgical procedure. While at this printing it is

unclear whether pending legislation before Congress will revitalize the prohibition on physician ownership of specialty hospitals, these comments suggest that specialty hospitals are likely to continue to receive heightened attention from CMS irrespective of any further legislative action.