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Lynn Shapiro Snyder, Esq.
EDITOR

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The "Agony" and the "Ecstasy" Continues With Issuance of Final Phase III Stark Regulations[1]

On September 5, 2007, the Centers for Medicare and Medicaid Services ("CMS") issued, in final, the long awaited Phase III Regulations (the "Phase III Regulations") to the Federal Physician Self-Referral Law (commonly referred to as the "Stark Law"). *See* 72 Fed. Reg. 51,012 (September 5, 2007). The Phase III Regulations, which take effect on December 4, 2007, include some good news (the "ecstasy") and a great deal of bad news (the "agony") for health care organizations that furnish designated health services ("DHS") through financial arrangements with referring physicians.

Although the number of modifications to the regulatory text itself is modest, the significance of the regulation lies more in the sweeping changes in interpretation contained in the regulation's preamble, which runs more than sixty five pages in the Federal Register. For example, the addition of a single word (*e.g.*, "directly" with respect to independent contractor arrangements) is expected to have a profound impact on many common arrangements involving physicians in the health care community, arrangements which were thought finally to have been protected via the final Phase II Regulations.

With an effective date of December 4, 2007, this issuance will set off yet another round of restructurings in the health care community, at a time when many would argue that the health care community should be focusing on larger issues such as health care access and quality. Group practices that structured their compensation formulas to meet the Phase II standards in 2004 now will need to revisit and possibly modify their methodologies yet again before year end. Academic medical centers and other hospital systems will need to review their faculty practice plan and affiliated group practice arrangements in light of the new "stand in the shoes" criteria and "indirect" arrangements restrictions. Organizations' policies on amending physician contracts may need to be revamped in light of new interpretations of "set in advance" requirements that potentially limit the ability to make changes to meet legitimate business needs. All in all, the Phase III Regulations reflect a return to governmental micromanagement of physician arrangements that the Phase II Regulations were supposed to have left behind.

[1] EBG previously published an extensive analysis and discussion of the final Stark II Phase I Regulations in 2001, entitled ***The Agony and the Ecstasy of the Final Stark II Regulations.*** Copies of this prior publication are available from EBG upon request.

Especially troubling is CMS's selective adherence and divergence from its own Medicare coverage and payment rules. CMS pronounces in the preamble to the Phase III Regulation that its interpretations are part of an overall policy of Stark regulations following the Medicare coverage and payment rules but at the same time CMS diverges from these coverage and payment rules in various situations. For example, the Phase II Regulations allowed group practice physicians to be compensated based directly on in-office ancillary services, but now in Phase III CMS has flip-flopped on that position. CMS in Phase III, citing Medicare coverage and payment rules, says that this is because the Medicare rules no longer consider most DHS that are separately Medicare covered to be "incident to," even if physicians satisfy the higher direct, personal supervision requirements of "incident to" services. Yet CMS specifically declines to follow the Medicare billing rules in other key areas. For example, Phase III Regulations now require that independent contractor supervision must be "on the premises" for Stark Law purposes, despite recent statutory modifications that relaxed Medicare billing limitations on independent contractor services furnished off premises. Similarly, Medicare rules now recognize and permit "leased" employee relationships — that is, individuals contracted from another entity — for supervision of "incident to" services, but the Phase III Regulations now only allow "direct" contracts with physicians for this purpose.

Another key aspect of interpretation that has drastically changed from Phase I to Phase II to Phase III concerns the status of contracted physicians in a group practice. As a result, these arrangements have had to be restructured every few years as CMS's position has changed back and forth over how contracted physicians can be compensated and whether they can supervise services for a group practice's patients.

There is, however, some "ecstasy" in the Stark III Regulations, including CMS's positive interpretations related to covenants imposed on physicians recruited to join medical groups, clarification on the Academic Medical Center ("AMC") exception, and the expansion of the recruitment exception to federally qualified health centers and rural health clinics. CMS also provides certain limited accommodations for inadvertent non-monetary payments to physicians in excess of the required limits and provides the opportunity for certain indirect compensation arrangements to continue until expiration of their current or renewal term before restructuring may be required.

The Phase III Final Regulations were in addition to a number of modifications CMS proposed concerning the Stark regulations issued separately in July 2007 as part of CMS's Calendar Year 2008 proposed Medicare Physician Fee Schedule ("CY2008 MPFS") *See* 72 Fed. Reg. 38,122 (July 2, 2007).[2] These proposed regulations included a number of significant provisions related to services furnished "under arrangements"; the anti-markup rule related to purchased interpretations; unit-of-service (per-click) payments in space and equipment leases; percentage-based compensation arrangements; a new and more expanded "stand in the shoes" rule than that proposed in Phase III — *i.e.*, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties an and on the same terms as does the entity that it owns or controls; and alternative criteria for satisfying certain exceptions.

[2] EBG submitted comments to CMS on the provisions in the CY2008 MPFS proposed regulations related to Stark, which can be found at http://www.ebghealthlaw.com/practices.php?p_id=8#STARK.

While the CY2008 MPFS provisions were published as a proposed rule, it is unclear when (and to what extent) these provisions will become effective. At the same time, the Phase III Regulations were issued in final and become effective on December 4, 2007.[3] Although CMS makes the statement in the preamble that the Phase III Regulations do not "require existing financial relationships to be restructured," as set forth above and also in connection with the MPFS proposed modifications, there do, in fact, appear to be revisions that health care entities and physicians will need to make in order to comply. Despite a December 4 effective date for the Phase III Regulations, it is currently unclear whether an organization should completely restructure any such arrangements strictly with the Phase III Regulations in mind or whether the provisions in the MPFS could be finalized in the near future that would require substantial restructuring. Moreover, both the Phase III and CY2008 MPFS rules foreshadow substantial further restrictions in the regulations in future rulemakings.

The Phase III Regulations also raise substantial questions regarding CMS's adherence to appropriate administrative procedures. How can a final regulation change a prior final regulation without an opportunity for review and comment of a proposed regulation? It is one thing to clarify a final regulation to grant greater flexibility; it is quite another to retract flexibility that was already granted in final form. Courts typically give deference to the interpretation of the regulatory agency, but should they do so when that interpretation changes fundamentally every two years? For practical purposes how can a Stark "violation" of an ever-changing interpretation form the basis of any boot-strapped false claims action? In other words, we question whether parties can be held accountable for acting with knowledge or reckless disregard in their arrangements under a regulatory standard that keeps changing.

Despite the fact that during the last decade there have been three separate "phases" of final (or interim final) regulations issued concerning the Stark Law, there still remain many significant, unanswered questions concerning elements of Stark Law compliance. A few of these issues, which are addressed below, include the application of the Stark Law to the State Medicaid Programs, the extent to which CMS will begin issuing more advisory opinions on specific proposals under the Stark Law, the current status of the "whole hospital" exception, and the interrelationship between the Phase III Regulations and the recently proposed modifications to aspects of the Stark Regulations included in the proposed CY2008 MPFS. Clearly, we can expect additional "phases" to continue to be published.

Following a brief overview of the history of the Stark Law and its regulations, this Special Alert describes some of the key provisions that are included in the Phase III Regulations, identifying both the "agony" and "ecstasy" of the Phase III requirements and defining important areas of Stark Law compliance that remain unsettled.

Background of the Stark Law and Its Regulatory History

In 1989, Congress adopted the "Stark I" statute applicable to entities providing Medicare-covered clinical laboratory services, and which became effective January 1, 1992. Then, in 1993, the Stark Law was broadened ("Stark II") to apply to the provision of Medicaid services and to a list of "designated health services" that included not only clinical laboratory services but also: physical therapy services; occupational therapy services; radiology (including magnetic resonance imaging, computerized axial tomography scans,

[3] Separately, we wonder why the effective date of the Phase III Regulations was not December 31, 2007, when many contracts structured under the Phase II rules would expire by their own terms anyway at the end of the calendar year.

and ultrasound services); radiation therapy services and supplies; DME and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.

Two years later, on August 14, 1995, CMS published final regulations implementing the Stark I prohibition against the ordering of clinical laboratory services from an entity with which a physician has a financial relationship (the "Phase I Regulations"). Three years after that, on January 9, 1998, CMS published as a proposed rule for public comment the "Phase II" Regulations (the "Phase II Proposed Regulations").

On January 4, 2001, almost three years to the day after the Stark II Proposed Regulations were issued, CMS published in the *Federal Register* the final "Phase I" of the Stark II Regulations (the "Phase I Regulations"). On March 26, 2004, CMS published the Phase II Regulations as an interim final rule with comment period and on September 5, 2007, CMS published Phase III of the Final Stark Regulations with an effective date 90 days following publication in the Federal Register. In the interim, CMS issued the CY2008 MPFS, which as stated above, included a number of proposed changes to the Stark Law.

Discussion of Key Issues in Phase III Regulations

Fair Market Value

The definition of fair market value ("FMV") is a key compliance element of many exceptions to the Stark Law, including but not limited to the exceptions for employment, personal services, academic medical centers, and, of course, the fair market value exception itself. Therefore, any regulatory changes to the FMV definition or CMS preamble discussion relating to FMV will have substantial impact on the industry.

In the Phase III Regulations, CMS removes the "safe harbor" for hourly payments to physicians for their personal services. This safe harbor was added in Phase II and included two methodologies that, if used to calculate hourly rates, would be deemed to be FMV for purposes of determining compliance. The methodologies were based on either (1) the hourly rate for emergency physician services in the relevant market or (2) an average of compensation for physicians in the same specialty at the 50th percentile using certain specified salary surveys. Based on public comments, CMS decided to eliminate this "safe harbor" provision because several of the designated surveys were no longer published or not readily available and the antitrust laws limited the feasibility of obtaining rates paid for emergency room physicians at competitor hospitals.

The elimination of a safe harbor that is not truly available is helpful, especially in light of the negative presumptions that failure to meet a safe harbor creates in government investigations. However, CMS now has gone in the other direction, seemingly reserving the right in all instances to second-guess both the methodology and amount of fair market value. CMS tells us in Phase III that it "cannot comment definitively on particular valuation methodologies", but that parties should determine fair market value based on "any commercially reasonable methodology that is appropriate under the circumstances" and that the appropriate methodology will depend on "the nature of the transaction, its location, and other factors." 70 Fed. Reg. at 51,015-16.

CMS's position in the Phase III preamble is that "[r]eference to multiple, objective, independently published salary surveys remains a prudent practice" for evaluating. However, is CMS suggesting that parties should not be comfortable using a single outside resource, such as an MGMA salary survey, to

determine physician compensation? If so, this contradicts both standard operating procedures in the industry and prior CMS pronouncements, *e.g.*, the Phase I preamble discussion of FMV that makes no reference to any need for there to be multiple surveys versus reliance on single outside sources. In Phase III, CMS also makes statements to the contrary, noting that nothing precludes parties from calculating FMV using "any commercially reasonable methodology" that is appropriate under the circumstances and otherwise meets the Stark law requirements. CMS continues that, as explained previously in Phase II, "good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party's intent, [but] it does not establish the ultimate issue of the accuracy of the valuation figure itself . . . " (72 Fed. Reg. at 51,015). Thus, CMS appears to be reserving the right to second guess the basis used by parties in good faith to establish compensation and to challenge reliance on single outside sources to determine fair market value payments.

The Phase III Regulations' preamble also states that a FMV 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 work is fair market value for the administrative work performed" (72 Fed. Reg. at 51,016). CMS goes on to state that the FMV for administrative services may differ from the FMV for clinical services. This commentary ignores the fact that a physician may not be inclined to take on administrative work at a hospital's request for less than the hourly "opportunity cost" of clinical practice, meaning that the FMV rate for administrative services as envisioned by CMS may not be sufficient to actually get a physician to agree to provide the necessary services.

CMS also cites with approval a FMV hourly rate used to determine annual salary, provided that the multiplier used in the calculation accurately reflects the number of hours "actually worked" by the physician. But this discussion puts into question annual salary compensation determined in advance, as the regulations contemplate, by multiplying a FMV hourly rate by a *projected* number of hours estimated to be required to perform the services during the year – *e.g.*, a medical director agreement that pays a fixed annual amount based on a projected number of hours worked per month, *i.e.*, 20 hours/month. Is CMS suggesting that parties using annual compensation methodologies should include an end-of-year reconciliation to adjust total annual compensation to the actual number of hours worked during the prior year by the physician? This ignores the fact that parties' failure fix "aggregate" annual compensation in advance means that the arrangement will not qualify for safe harbor protection under the Federal Anti-Kickback Statute ("AKS") which, CMS states throughout the preamble to the Phase II and Phase III Regulations that Stark compliance does not offer AKS protection.

Temporary Non-Compliance and Prohibition on Billing for Referrals from Physicians in Non-Exempt Arrangements

In Phase II, CMS added a provision that allows entities to submit claims and receive payments for DHS during certain periods of temporary noncompliance, but only if the arrangement had been in full compliance for a period of 180 consecutive calendar days preceding the date the arrangement became noncompliant, the relationship fell out of compliance due to reasons "beyond the entity's control", the entity promptly moved to rectify the noncompliance (which does not exceed 90 days), and the entity uses the non-compliance provision no more than once every 3 years for the same physician (except that there is no allowable period of non-compliance for arrangements falling under the exceptions for non-monetary compensation or medical staff incidental benefits).

CMS makes clear in the Phase III preamble that arrangements that were never in compliance cannot satisfy the temporary non-compliance requirements. In this regard, CMS discusses that a hospital that has an immediate need for ER coverage before it can get a formal written contract executed with a physician cannot take advantage of the temporary non-compliance provisions. 72 Fed. Reg. at 51,025. In the Phase III preamble, CMS provides a laundry list of documentation that entities should maintain for financial relationships that fall out of compliance. This list includes the following:

- The terms of the arrangement;
- Whether and how an arrangement fell out of compliance with a particular exception;
- The reasons for the arrangement falling out of compliance;
- Steps taken to bring the arrangement into compliance;
- Relevant dates; and
- Other similar information.

Because this list of supporting documentation is found in the preamble and not in the regulations, the question is whether parties that fail to create and maintain this exact list of materials will be deemed out of compliance with the rules regarding temporary non-compliance.

No where in the regulations or preamble does CMS delineate what will qualify as reasons for non-compliance "beyond the entity's control." CMS mentions loss of HPSA designation as an example, but leaves open whether other regulatory changes — such as the issuance of the Phase III Regulations themselves — qualify. For instance, what about an arrangement that qualified for an exception under the Phase II Regulations but will no longer qualify under CMS's interpretations stated in the preamble to the Phase III Regulations — can the parties to such arrangement take advantage of the temporary non-compliance exception's 90-day opportunity to cure starting as of the effective date of Phase III on December 4, 2007?

The provision for 90-day temporary non-compliance is available for all arrangements and is in addition to the 6-month holdover provisions specifically adopted for office and equipment leases. The office and equipment lease holdover provisions allow a month-to-month holdover rental for up to 6 months immediately following expiration of an agreement that met the conditions of the office or equipment exception, as applicable, provided the holdover rental is on the same terms and conditions as the immediately preceding agreement. *See* 42 C.F.R. 411.357(a) and (b).

These provisions for temporary non-compliance and holdover leases bear on the fundamental question of whether a Stark law violation outside of the narrowly defined regulatory parameters can ever be "cured" by ending the period of non-compliance and re-structuring the arrangement to remove the violation. So, for example, assume that parties discover that payments made to a physician exceeded FMV, and seek to have the physician repay the excess amounts so to bring the arrangement retroactively into compliance. The temporary non-compliance provisions would not be available, because the problem in this scenario was not caused by reasons beyond the hospital's control.

In contrast, what if the excess payments were made by mistake, for example, a personal services contract terminated but the hospital's accounting department mistakenly omitted to drop the physician from the direct deposit process for several payment cycles before the physician realized the error and notified the hospital? In principle, this should be a scenario that qualifies for temporary non-compliance but the Stark temporary non-compliance rules would not be available, even if the physician promptly repaid, because the problem was not caused by reasons outside the hospital's control.

By authorizing certain periods of temporary non-compliance, CMS suggests — but does not squarely address — whether any other scenarios of non-compliance can be remedied or whether they would constitute de facto violations. However, if the remedy is effective under general legal principles to set the parties back to the status quo ante, *e.g.*, the physician repays excess amounts in our scenario above, then why shouldn't that be good enough under the Stark Law, especially when the remedy is effectuated voluntarily and before any governmental inquiry has occurred?

Special Rules on Compensation

CMS confirms in the Phase III preamble that percentage compensation arrangements can be "set in advance" as long as the specific formula for calculating the compensation is set in advance and the compensation does not take into account the volume or value of referrals or other business generated. In addition, CMS states that under Phase III, entities may continue to use unit-based and percentage-based compensation arrangements.

However, the recently proposed changes to the Stark regulations included in the CY2008 MPFS would modify the Stark space and equipment lease exceptions to exclude unit-of-service based payments to a physician lessor for services rendered by an entity lessee to a patient who is referred by a physician lessor to the entity, on the theory that such arrangements are inherently susceptible to abuse because the physician has an incentive to profit from referring a higher volume of patients to the lessee. 72 Fed. Reg. at 38,183. This is in direct contrast to CMS's prior discussion of this very same topic. In Phase I of the Stark Regulations, CMS stated that it had "reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals." 66 Fed. Reg. at 876.

Application of Anti-Kickback Statute

In the Phase III Regulations, CMS continues to adhere to its position that it will not provide blanket Stark Law protection for an arrangement that satisfies all the requirements of a safe harbor under the AKS. This is a source of continuing confusion and frustration to the health care community, especially in areas in which CMS has proposed exacting standards for Stark Law protection which, even if met, still leave AKS exposure according to CMS. Areas such as AMCs and group practice structure and operations, which have Stark law exceptions but no corresponding AKS safe harbors, are particularly impacted.

Despite this lack of coordination between the AKS standards and safe harbors and the Stark Law exceptions, CMS continues to require AKS compliance in many of its Stark Law regulatory exceptions. This leaves a gaping hole in the bright line standard that the health care community needs with respect to

the Stark Law, especially given the government's position that Stark Law liability is an absolute "black and white" matter.

Group Practices/In-Office Ancillary Services

"Stand in the Shoes"

Under prior Stark regulations, financial arrangements between an intermediary physician group or other entity and a DHS entity were analyzed to determine, first, whether the arrangement constituted an "indirect compensation arrangement" under the Stark regulations definition and, second, if yes, whether the arrangement met the exception for indirect compensation arrangements. *See* 42 C.F.R. § 411.354(c)(2); 42 C.F.R. § 411.357(p). The analysis generally turned on whether the physicians at the other end of the "chain" of arrangements were paid based in any manner on the volume or value of referrals to the DHS entity. Under a technical analysis of the prior regulations, therefore, arrangements where the physicians were not paid based on referrals arguably fell outside of the Stark Law altogether.

In the preamble to the Phase III Regulations, CMS expressed "concern" about parties applying this type of analysis. The Phase III Regulations introduce a "stand in the shoes" concept to close this "unintended loophole" by treating compensation arrangements between DHS entities and group practices as if the arrangements are with the referring physicians. 72 Fed. Reg. at 51,028. The "stand in the shoes" concept was previously discussed in the preamble to the Phase II Regulations in which CMS responded to commenters who requested permission to use a "stand in the shoes" concept to qualify for an exception. At that time, CMS's stated position was that converting indirect arrangements to direct arrangements is "inconsistent with the compensation exceptions as drafted." 69 Fed. Reg. at 16,060.

Now, however, CMS has reversed its prior interpretation of its own regulations by specifically adopting in Phase III a "stand in the shoes" rule. Under this requirement, a physician "stands in the shoes" of his/her "physician organization" and is deemed to have the same compensation arrangement, with the same parties and on the same terms, as the physician organization. A "physician organization" means a physician (including a professional corporation of which the physician is sole owner), a physician practice, or a group practice that complies with the regulatory requirements for group practices. 42 C.F.R. § 411.351. A "physician practice" as used in this definition is not defined.

The effect of this new provision is twofold: (1) it renders some arrangements that would have constituted indirect compensation arrangements under Phase II to now be direct compensation arrangements that must meet an exception and (2) it brings back within the purview of the Stark Law arrangements that did not implicate Stark at all under the prior regulations. A fundamental distinction between the indirect exception and other potentially relevant direct exceptions is that "indirect" compensation is not subject to the requirement that it be "set in advance" for one year, giving parties substantial latitude in establishing and amending their arrangements to meet immediate business needs, so long as hose modifications are not based on the volume or value of referrals.

Because the "stand in the shoes" concept would make certain existing arrangements problematic, the Phase III Regulations state that the "stand in the shoes" rules "need not apply" during the original term or current renewal term of an arrangement that satisfied the requirements of the exception for indirect

compensation arrangements as of September 5, 2007 (*i.e.*, the publication date of the Phase III Regulations). However, this "grandfathering" of certain current arrangements does not protect existing arrangements that are now subject to the "stand in the shoes" rule but that previously fell outside of Stark because they did not meet the definition of an "indirect compensation arrangement" under the Phase II Regulations. Nonetheless, parties that previously took a conservative "belt and suspenders" approach by structuring arrangements as if a direct exception applied should not find significant restructuring required under Phase III.

CMS further states in the Phase III preamble that it is not making changes to the treatment of arrangements that, after application of the "stand in the shoes" provision, still do not meet the definition of a compensation arrangement, and so will require analysis under the indirect compensation provisions. CMS cites as examples arrangements involving an intervening entity other than a physician organization, such as a "chain" of arrangements that runs "DHS entity to management company to referring physician," or where there is more than one intervening entity, such as a "chain" that runs "DHS entity to management company to group practice to referring physician." 72 Fed. Reg. at 51,028. CMS specifically asks here for additional public input on the best way to apply a "stand in the shoes" rule to these indirect relationships. CMS confirms that based on the new "stand in the shoes" provision, the financial relationship at issue is the direct relationship between the hospital and the group practice, which could satisfy the requirements of any applicable direct compensation arrangements exception. 72 Fed. Reg. at 51,062.

An interesting comment in the preamble to Phase III focuses on a source of potential hospital knowledge concerning physician financial relationships. "Knowledge" is a key compliance element of the indirect compensation arrangements definition. CMS says that any information in the "possession" of the hospital may be relevant to whether the hospital knew or should have known about an indirect financial relationship with a referring physician. CMS makes these comments in response to a comment about whether information disclosed on a conflict of interest form constitutes knowledge. CMS responds by equating "possession" with "knowledge." 72 Fed. Reg. at 51,030.

CMS in the Phase III preamble confirms with regard to those indirect compensation arrangements which cannot fit in any of the direct compensation arrangements exceptions, the only available exception is the indirect compensation arrangements exception. Further, it is not necessary for each link in the chain of financial relationships to also satisfy the requirements of a separate exception — the *only* financial relationship that triggers liability under the Stark Law is the financial relationship between the DHS entity and the referring physician.

We note that CMS proposed in the CY2008 MPFS regulations to expand the "stand in the shoes" concept to DHS entities that "own or control" an entity to which a physician makes a DHS referral. 72 Fed. Reg. at 38,184.

The Stark Law and implementing regulations always have been concerned with ***financial*** relationships, *i.e.*, ownership interests and compensation arrangements yet the proposed CY2008 MPFS regulations would expands the relationships implicating the Stark Law beyond the statute to "control" of affiliated organizations. Nowhere in the Stark statute does it mention "control." Moreover, "control" is an ambiguous concept that has no place in the Stark Law, where clarity and precision are essential. What would constitute control? A membership interest? A management/contractual arrangement? Board seats?

If so, how many? Even ownership under a "stand in the shoes" concept is difficult. Does it only apply to wholly owned entities? If some lesser percentage of ownership than wholly owned, is a majority interest necessary to trigger "stand in the shoes?" If the DHS entity owns a 40% interest, is that sufficient "ownership" to require the entity to "stand in the shoes?" As set forth in EBG's comments to CMS, we find this proposal to be highly problematic.

Special Issues for Foundation-Model Organizations

In light of the "stand in the shoes" concept in physicians' relationships, it is puzzling that CMS continues to fail to recognize foundation-model group practices — that is, foundations that furnish and bill for DHS and contract with a physician group to furnish substantially all of the foundation's physicians services. CMS says that structures can qualify as group practices if the group practice entity furnishes and bills for DHS, but that type of structure would not include a foundation-model group. Clearly, if CMS is going to collapse certain entities that are substantially affiliated with one another, *e.g.*, the "stand in the shoes" concept," and is considering collapsing more entities under the same theory (*See* CY 2008 MPFS Proposed Rule), then foundation-model groups ought to be considered first on the list for such treatment. This is especially so in light of the clear statutory language in the group practice definition explicitly recognizing foundations as one type of group practice. In fact, CMS uses medical foundations as an example in its CY 2008 MPFS Proposed Rule, explaining that under the proposed expansion of the "stand in the shoes" concept, a hospital would "stand in the shoes" of a medical foundation that it owned or controlled and that contracted with physicians to provide services at a clinic owned by the foundation. 72 Fed. Reg. at 38,184.

Also relevant to foundations is the CMS preamble discussion to the personal services exception, where CMS addresses two hypotheticals. The first hypothetical involves a hospital that contracts with a group practice for the provision of services. The second hypothetical involves a medical foundation that contracts with a group practice. CMS explains that since it now considers physicians to "stand in the shoes" of their physician organizations, the physicians would stand in the shoes of the group practice that employs them and would be considered to have direct compensation arrangements with the hospital or medical foundation from the two hypotheticals. Thus, CMS explains, in the first hypothetical situation, the financial relationship between the hospital and the physician who is standing in the shoes of the group practice must meet an exception in order for the physician to refer patients to the hospital. 72 Fed. Reg. at 51,047. However, CMS continues, if the hospital contracts with a medical foundation that, in turn, contracts with the group which employs the physicians, who stand in the shoes of the group, compliance with the indirect compensation exception would be necessary. If a physician makes a referral to the medical foundation's clinic, as opposed to the hospital, for DHS furnished by the clinic, then the relationship between the physician standing in the shoes of the group practice and the clinic would be deemed to be a direct financial relationship.

Physicians in the Group

CMS in Phase III has revised the definition of "physician in the group practice" to "clarify" that an independent contractor must furnish patient care services pursuant to a contract made ***directly*** with the group practice in order for the physician to qualify as a "physician in the group practice."

Previously, physicians with contractual arrangements could qualify as "physicians in the group" but not necessarily as "members" of the group, but the Stark regulations did not precisely dictate how the contractual arrangement should be structured, leaving open the possibility for contracting though another entity. In Phase III, CMS makes an explicit requirement that independent contractors have a direct contractual arrangement with the group. CMS specifically says in the preamble that the definition of "physician in the group practice" does not extend to contractors between the group practice and another entity, such as a staffing company. 72 Fed. Reg. at 51,018. The significance of being a "physician in the group" is that such physicians are included for purposes of determining whether the group qualifies for Stark Law protection under several of the criteria applicable to group practices.

CMS explains that group practices receive favorable treatment under Stark and that a group's physicians must have a "strong and meaningful nexus" to the group. CMS states its belief that an independent contractor in "direct contractual privity" with a group practice has such nexus, while leased employees do not. CMS expresses concern in particular about "potentially abusive arrangements" where a physician is employed by (and receives one W-2 form) a staffing company that leases the physician to numerous group practices, none of which enters into an individual contract with the group, but all of which consider the physician a "physician in the group." Therefore, many physician groups that have contracted with other medical practices and have not had individual contracts with each of the individual physicians will need to revisit and revise these arrangements prior to the December 4, 2007 effective date of the Phase III Regulations.

CMS also limits the scope of services allowed to be furnished to a group by independent contractor physicians to services "on" the group's premises. This is yet another example of CMS's selective divergence from Medicare payment principles to narrow the scope of the Stark Law exceptions, despite CMS's stated position in the "incident to" context that Stark definitions should follow Medicare coverage and payment criteria in order to avoid "confusion."[4]

"Incident To" Services

Undoubtedly, one of the most confusing, yet recurring, questions that healthcare organizations ask is whether physicians may receive compensation based on services billed as "incident to" physicians professional services or other services supervised by physicians. This issue arises because the Stark statute defines a "group practice" eligible for the in-office ancillary services exception as one in which no physicians are paid directly or indirectly based on referrals, but in which physicians receive productivity bonuses based on personally performed services and services "incident to" personally performed services. In contrast, physicians compensated under the employment, personal services or AMC exceptions may be compensated for personally performed services, but not "incident to" services as they are now defined in Section 60.1 of the CMS Internet-only Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services). 72 Fed. Reg. at 51,023.

The question of whether physicians in a group can be paid based on "incident to" services is one in which CMS has changed its position over the years and the answer currently depends, in part, on what

[4] *See* 72 Fed. Reg. at 51,016. Medicare coverage and payment rules on reassignment were modified by Congress in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") specifically to allow a physician to reassign payment to a group regardless of the location where the physician furnishes his/her services for the group.

types of supervised services are involved and which Stark Law exception the parties are seeking to comply with. A "referral" for DHS is defined to exclude services personally performed by a physician, but to include services performed by a physician's employees (or any other person, such as an independent contractor or another member of the physician's group practice. The Phase III Regulations make clear that as far as "incident to" services are concerned, those services now expressly include supplies, not just services, namely, drugs.

In addition, the Phase III Regulations define "incident to" services by explicit cross reference to the relevant sections of CMS's Medicare Benefit Policy Manual. CMS declines to expand the definition of "incident to" services for Stark Law purposes beyond the technical definition applicable under general Medicare coverage and payment rules. CMS also makes clear that services covered by Medicare under a separate benefit category, such as diagnostic x-ray tests, diagnostic laboratory tests and other diagnostic tests, do not qualify as "incident to" services under Medicare coverage and payment rules and, therefore, also do not qualify under the Stark Law. CMS cites in its Phase III preamble discussion to its prior Calendar Year 2003 Medicare Physician Fee Schedule ("CY2003 MPFS") as support for its position in the Phase III Regulation, and CMS specifically declines to expand the definition of "incident to" for Stark purposes beyond the definition applicable for Medicare payment and coverage. Yet, in its discussion of arrangements between group practices and independent contractor physicians, CMS willingly diverges from the more flexible Medicare coverage and payment rules on reassignment mandated by Congress to impose stricter "on-site" limitations under Stark. This is another example of CMS's selective reliance on Medicare interpretations only to the detriment of Stark Law flexibility. Moreover, a close review of the CY2003 MPFS preamble shows that CMS specifically "decline[d]" to prohibit a separately and independently listed service from being furnished as an "incident to" service." Instead, CMS reiterated that a separately and independently listed service need not meet the requirements of an "incident to" service. 67 Fed. Reg. at 79,994. We fail to understand why CMS prevents the Stark regulations from also authorizing such flexibility, especially since Congress enacted the statutory "incident to" language well knowing the full range of designed health services furnished "incident to" in a group practice setting, and eligible for productivity bonuses. This CMS position raises substantial issues regarding the procedural propriety of CMS altering longstanding Medicare regulatory definitions and using such alterations to fundamentally restrict the scope of Stark statutory exceptions adopted with those regulatory exceptions in mind. At a minimum, such a step would require a proposed rulemaking, with notice and an opportunity for comment, not simply a unilateral retraction of prior positions.

As a result, a group practice physician can receive a bonus based on physical therapy or outpatient prescription drugs, which can be billed as "incident to" the physician's professional services, but such physician cannot receive a productivity bonus directly related to any other DHS referrals, such as "diagnostic tests" or "hospital admissions." These rules disregard the fact that diagnostic tests often are performed under the direct personal supervision of a physician, similar to the administration of drugs, and suggest inaccurately that group practices previously could pay physicians based on hospital admissions. The new rules also underestimate the sheer complexity of accounting for "incident to" versus directly covered services. In the drug area alone, groups will now need to account separately for infusion services still covered and paid solely as an "incident to" services versus oral drugs for the same purpose, oral antiemetics and other enumerated covered drugs furnished in their offices.

The group practice rules additionally allow physicians in a group to be paid based on profitability. This is a separate type of compensation formula authorized by the group practice rules in addition to the direct bonus allowed for productivity and "incident to" services, discussed above. In Phase II, CMS stated that "[w]e have revised the regulations to make clear that profit shares or productivity bonuses can be based directly on services that are "incident to' the physician's personally performed services." 69 Fed. Reg. at 16,050. Now, in a reversal, CMS in Phase III says that this prior Phase II statement is withdrawn, because the Stark statute only includes bonuses paid for "incident to" services in the context of productivity bonuses. This means that "incident to" services can be taken into account in awarding profitability bonuses under the group practice rules only in a manner that is not directly related to DHS referrals, that is in accordance with one of the protected methodologies set forth in the regulations. 72 Fed. Reg. at 51,024.

In-Office Ancillary Services

In the preamble to Phase III Regulations, CMS characterizes the in-office ancillary exception as "one of the most important exceptions" to the physician self-referral rule. 72 Fed. Reg. at 51,032. In general, the in-office ancillary services exception allows a physician or a group practice to order and provide DHS (other than most DME) in the office, provided the DHS is "truly ancillary" to the medical services furnished by the group. CMS says that it makes "no substantive changes" to the in-office ancillary services exception as part of Phase III, but that it responds in the preamble to "issues of concern" to commenters. Clearly, it is significant that CMS declines to make any substantive changes to the in-office ancillary services exception despite the evolution of other Medicare policies in the billing context to grant more flexibility for independent contractor relationships.

Specifically, CMS says that the Stark Law does not "supersede" Medicare payment and billing rules and policies, including rules on reassignment, supervisor, or purchased diagnostic tests. For example, following enactment of the MMA, CMS permitted independent contractor physician to reassign to an entity his or her right to bill Medicare, regardless of whether the services were performed at the entity's premises. However, CMS continues in the Phase III Regulations to require that the services performed by the independent contractor physician must be performed "in" the group practices facilities, CMS states, notwithstanding Congress' MMA mandate to the contrary. 72 Fed. Reg. at 51,034.

What is even more significant is that CMS foreshadows future limitations on the scope of the in-office ancillary services exception. CMS forewarns that it is "considering" whether certain types of arrangements — such as those involving in-office pathology labs and sophisticated imaging equipment — should continue to be eligible for protection under the in-office ancillary services exception. Removing these categories of services from protection would be a significant adverse development for physician groups. Also, given Congress' specific statutory delineation of what services may be rendered under the "in-office" exception (*e.g.*, not DME other than infusion pumps, and not parenteral and enteral equipment, services and supplies), this proposal raises the question whether such prohibition would be within CMS's authority.

CMS also sheds some additional light on how it would assess whether "some" physician services unrelated to DHS are being furnished in the "same" building, as required by the in-office ancillary services exception. In essence, CMS provides no bright line test, but instead reserves for itself the right to

determine whether the "same services" provided by a group are enough. For instance, CMS states that it would "take into account the nature of the group's overall practice . . ." citing, for example, the specialties of the practice, and the physician's full range of practice. CMS explains that creating a satellite office that "appears" to satisfy the "same building" test but is in fact "merely a sham arrangement" will result in "claims denial." CMS offers the example that renting office space part-time in a free-standing imaging facility "purportedly to provide physician services" unrelated to DHS at the facility location would be considered a sham if few or no such services were "actually contemplated or provided." CMS goes on to state that "[a]s we have stated in other contexts, the operation of an arrangement, not is form on paper, is determinative." 72 Fed. Reg. at 51,033.

Interestingly, CMS discusses how the practice of telemedicine is to be covered in assessing compliance with the "same building" test. CMS states that where a physician who is located in a different location from the patient orders an item/service to be furnished at the location where the patient is located, the physician's time spent performing telemedicine services is counted as time spent "in the location where the physician is physically present." 72 Fed. Reg. at 51,033. It is not clear why CMS felt the need to take a position at this level of micromanagement of medical practice.

On another issue, CMS characterizes "part-time, shared, off-site" facilities as being readily subject to abuse. 72 Fed. Reg. at 51,033. To address this "obvious potential for abuse," CMS refers to CY2007 MPFS proposed regulations where it proposed additional requirements for the centralized building test. 71 Fed. Reg. 49,056-49,097. In the meantime, in the Phase III preamble, CMS "cautions" parties with shared facilities in the same building or off-site arrangements that they must comply with the in-office ancillary services "in operation, not only on paper." In other words, CMS says, "compliance is required with respect to every DHS claim filed." 72 Fed. Reg. at 51,033. CMS continues that "condominium" arrangements are "particularly vulnerable to non-compliance," and "staff and operations at the off-site facilities should be closely monitored." For example, CMS says, a supervising physician who is an independent contractor of a group practice must be "in the group practice's specific premises" at the "specific time" a DHS is furnished and supervised for a group practice patient. CMS adds that such arrangements raise "substantial concerns" under the AKS.

Academic Medical Centers

CMS says that the Phase III Regulations adopt the Phase II Regulations concerning AMCs with minor clarifications. However, the preamble to the Phase III Regulations includes a major clarification as to how faculty practice plans can compensate faculty physicians, specifically by allowing faculty plan physicians to be structured as group practices under the in-office ancillary services exception.

Previously, in the Phase II preamble, CMS stated that "all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform." CMS went on to explain that "group practices also may pay physician in the group, whether independent contractors or employees, productivity bonuses based on "incident to" services, as well as indirect bonuses and profit shares that may include DHS revenues , provided that the distribution methodology meets certain conditions." 69 Fed. Reg. at 16,067.

Now in the Phase III preamble, CMS states:

> Nothing in the regulations prevents a faculty practice plan from qualifying as a group practice if it can satisfy the conditions[of the group practice requirements] . . . If these conditions are satisfied, the faculty practice plan may avail itself of the physician services exception . . . and the in-office ancillary services exception . . . for DHS referrals within the faculty practice plan, as well as the special rule for productivity bonuses and profit shares [in the group practice rules]. We note that neither the physician services exception, nor the in-office ancillary services exception, would protect referrals by faculty practice plan physicians to other components of an academic medical center, such as the affiliated hospital. In such circumstances, the academic medical center exception may be useful.

72 Fed. Reg. at 51,023. CMS's updated position appears more consistent with the Stark statutory provision that specifically includes "faculty practice plans" within the definition of group practices.

Also helpful is the preamble confirmation that the exception for indirect compensation arrangements is "potentially applicable" to arrangements involving AMCs and physicians. 72 Fed. Reg. at 51,038. On the other hand, CMS states that the AMC exception is designed to "supplement — not supplant" other exceptions, such as the exemption for *bona fide* employment relationships and personal services arrangements. CMS states that to the extent a hospital or other entity cannot take advantage of the AMC exception, it should be able to structure its legitimate compensation arrangements with physicians to meet another exception.

CMS also states that it believes it is appropriate to treat physician compensation under the AMC exception the same as compensation for independent contractor physicians under the personal services exception, meaning that compensation is protected in the aggregate if the exception is met. 72 Fed. Reg. at 51,037. CMS clarifies that the actual dollar amount of the referring faculty physician's compensation need not be set in advance under the AMC exception; it is sufficient if the contribution of each component of the AMC to the aggregate compensation uses a methodology that qualifies under the exception. Further, CMS says, where a physician is paid by more than one component of the AMC, each such payment arrangement must not take into account the volume or value of referrals or other business generated by the physician within the AMC. However, CMS clarifies, the aggregate compensation (that is, total from all components) cannot exceed fair market value for the services provided. The exception does not require that compensation from each component satisfy a fair market value test, according to the preamble.

On the other hand, in the Phase III preamble, CMS describes how research funds are to be used. CMS states its position that any money paid to a referring physician for research must be used *solely* to support *bona fide* research or teaching, which are core academic medical center functions, and that research money cannot be used for indigent care or community service. 72 Fed. Reg. at 51,036. In addition, funds must be used in a manner that is consistent with the terms of the research grant in order for the funds to meet the AMC exception requirement that many spent on research must be *bona fide* research. Is CMS suggesting that grant compliance is a condition precedent to Stark Law compliance? The requirement that research be *bona fide*, on its face, does not require this. Other questions remain unanswered *e.g.*, what about payments to individual faculty members as compensation for them providing

a full array of faculty services that includes research along with clinical teaching, does the research portion need to be separately carved out and paid for? Why do the Stark regulations need to micromanage faculty relationships to this level in an effort to prevent improper referrals?

Finally, CMS leaves unanswered the question of whether a component of an AMC could be a "physician organization" for purposes of the "stand in the shoes" provisions, discussed above. If it does, this would mean that faculty physicians stand in the shoes of their employer within the AMC, perhaps a faculty practice plan? If so, this puts into question the extent to which an affiliated hospital component of the AMC can provide legitimate mission support to a faculty practice plan that employs the faculty physicians (which is how many AMC funds flow arrangements works) without conducting a fair market value assessment of the faculty physician services?

Ownership Interests In A Whole Hospital

The Stark Law provides the exception for DHS services provided by a hospital where the referring physicians has an ownership or investment interest in the hospital and not merely a subdivision of the hospital and the physician is authorized to provide services at the hospital. The MMA amended the statute to provide a moratorium on ownership or investment in a "specialty hospital" effective for the 18-month period starting on December 8, 2003. The moratorium expired on June 7, 2005.

In earlier versions of the Stark regulations, CMS explained that a physician can have an ownership or investment interest in a hospital by virtue of holding an interest in an organization, such as a health system, that owns a chain of hospitals that includes the particular hospital, because the statute does not require the physician to have a direct ownership or investment interest in the hospital. 72 Fed. Reg. at 51,042-51,043 citing to 63 Fed. Reg. at 1713.

The Phase III Regulations do not make any substantive changes to the "whole hospital' exception. However, CMS addresses certain issues relating to the exception in the Phase III preamble. CMS holds firm in its view that the statutory exception was intended by Congress to protect ownership and investment interests "in" a hospital "with respect to services furnished by the hospital." Therefore, CMS declines to modify the exception to protect any other services or subsidiaries. CMS specifically expresses that it does not believe that Congress intended to create a blanket exception for physician ownership in for-profit conglomerates which would, in CMS view, "intensify rather than diminish the incentive to refer due to increased profit opportunities. 72 Fed. Reg. at 51,043. At the same time, it seems inconsistent that CMS is attempting to require physicians to "stand in the shoes" of their physician groups yet at the same time not allow hospitals' subsidiary operations to "stand in the shoes" of their corporate parent.

Rental of Office Space and Equipment

The Phase III Regulations make no substantive changes to the text of the rental of office space exception and rental of equipment exceptions. However, the preamble to the Phase III Regulations substantially modifies the interpretation of the regulation's text in a way that micromanages lease administration and, by specific analogy, the maintenance of personal services arrangements, at a level of "firm over substance."

This is especially obvious in CMS's preamble pronouncements on the extent to which parties can amend agreements prior to the expiration of the current term and still remain in compliance with the exceptions. The Phase II Regulations provided that leases could be terminated without cause during the term of the agreement, but that no new agreement as to the subject matter of the lease could be entered into between the parties within the first year of the original lease term. CMS now states that because rental charges, including the methodology used to calculate rental charges, must be "set in advance," parties may not change the rental charges at any time during the term of the agreement even after the first year.

Instead, CMS suggests that parties wishing to change the rental charges must terminate the agreement and enter in a new agreement, as opposed to an amended agreement, with different rental charges and/or other terms. However, CMS warns, the new agreement may be entered into only *after* the first year of the original lease term has expired, regardless of the length of the original term, the new lease must be for a term of at least one year and must comply with all other criteria of the exception. 72 Fed. Reg. at 51,044. CMS does not explain how a new agreement differs from an amendment for purposes of these provisions. CMS goes on to explain that an amended agreement need not continue for an additional 1 year following its amendment if the original termination date of the agreement would occur sooner; rather, the amended agreement may terminate upon the original expiration date, provided that the original term is at least 1 year. CMS reminds us, however, that rental charges, or rental charge methodologies, may not be modified more frequently than once every year.

CMS explains that parties may amend a lease agreement multiple times during or after the first year of its term, provided that the rental charges are not changed and all other requirements of the exception are satisfied. However, changes to terms that are material to the rental charges, such as the amount of space leased, may cause the rental charges to fall out of compliance with the fair market value and "volume and value of referrals" requirements. For example, CMS suggests, if the original rental charges were $5,000 per month for 200 square feet of space and the amended lease added 100 square feet of space but did not require additional payment beyond the original monthly payment of $5,000, the rental charges under the new agreement likely would not be consistent with fair market value and may take into account the volume or value of referrals or other business generated between the parties. 72 Fed. Reg. at 51,044.

CMS explains that the prohibition on entering into a new lease agreement within the original term applies only to a new lease for "all or part" of the same office space. It does not prohibit the parties from entering into a personal service arrangement or a lease for completely different office space. 72 Fed. Reg. at 51,044. CMS also confirms its position that leases are not eligible for protection under the fair market value exception.

On the issue of office-sharing arrangements, CMS explains that the requirement for the lessee's exclusive use of the leased space/equipment when using it requires that shared leases be for established blocks of time. With respect to the use of common areas, the exception allows pro rata payments for common areas, but CMS explains that by common areas, it means foyers, central waiting rooms, break rooms, vending areas, etc., to the extent that the areas are, in fact, used by the sublessee (*e.g.*, a sublessee cannot pay rent for a break room that it will never use). CMS continues that common areas that contain certain limited equipment may be shared, such as hallways used by non-physician staff to weigh patients or draw fluid samples. CMS's examples of permissible equipment in shared common areas is limited to the

type that is "not usually separately leased (for example, scales)." CMS states that non-exclusive arrangements, other than for common space (as described above), do not satisfy the requirements of the lease exceptions. 72 Fed. Reg. at 51,045.

Still another leasing issue is the prohibition on the lessee's sharing of rented office space or equipment with the lessor or any person or entity related to the lessor. According to CMS, this includes group practices, group practice physicians or other entities "owned or operated by" the lessor. Determining whether a lessee is sharing space or equipment with a person or entity related to the lessor will require a case-by-case review of the facts. However, CMS says, nothing prohibits physicians from subleasing space or equipment from a hospital, a hospital-owned group, or physicians employed by a hospital, provided that the sublessee has exclusive use of the space or equipment that is the subject of the sublease and all other requirements of the exception(s) are satisfied. 72 Fed. Reg. at 51,045.

Tenant improvements are also addressed in the Phase III preamble. CMS says that for accounting purposes, tenant improvements should be accounted for in accordance with generally accepted accounting practices. For purposes of determining the FMV for rental charges, whether the costs of capital improvements should be allocated over the useful life of the improvements or be passed on in their entirety to the physician lessee who requested them will depend upon the facts and circumstances of the particular case. Specifically, if a lessor provides improvements for the benefit of a physician lessee that are unlikely to be chargeable to a subsequent tenant, the lessor should allocate the entire cost of these improvements to the lessee for whose unique benefit they are made. CMS concludes that improvements that the lessor reasonably expects would be chargeable to subsequent lessees may be allocated over their expected useful life. 72 Fed. Reg. at 51,045.

Finally, on the issue of holdover leases, the Phase III Regulations adopt the prior Phase II provisions allowing a month-to-month rental for up to 6 months following expiration of the agreement after at least one year. CMS in the Phase III preamble confirms that lessors can charge a holdover rental premium, provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with FMV and does not take into account the volume or value of referrals or other business generated between the parties. CMS declines to permit the holdover grace period to last for the length of time that the landlord is taking steps to evict the tenant as suggested by a commenter. CMS believes that the 6-month holdover period permitted in the regulations is sufficient. 72 Fed. Reg. at 51,045. CMS's statements that hold over premiums must "remain" consistent with fair market value does not reflect the reality that holdover premiums by definition are generally large amounts which have no basis in fair market value — *e.g.*, 50% or more of the lease rental amount.

Employment

Although there are no regulatory text changes to the *bona fide* employment exception, there are preamble comments worth mentioning with regard to this exception. Significantly, CMS states in the Phase III preamble an individual is considered an "employee" for purposes of the self-referral provisions if the individual is considered an employee under common law rules applicable to determining the employer-employee relationship under the Internal Revenue Code. CMS goes on to state:

> Whereas the receipt of a W-2 from an entity and the written terms of the arrangement are relevant, neither controls whether an individual meets the definition of "employee" for purposes of the physician self-referral law; rather, the focus is on the actual relationship between the parties.

72 Fed. Reg. at 51,014. By this language, is CMS reserving the right to make its own determination of whether an employee meets the common law IRS test or not, regardless of whether the parties believe and intended that an employment relationship be created? What is significant is that IRS rules generally attempt to find employment relationships for employment tax purposes even where the parties purport to structure an independent contractor relationship. Presumably, here, CMS would attempt to do the opposite — that is, question whether a W-2 employment relationship really should be required to meet the more stringent personal services exception standards applicable to contractors.

Personal Services Arrangements

The Phase III Regulations modify the personal services arrangements exception to allow a "holdover personal services arrangement" for up to six months following expiration of an agreement of at least 1 year that met the exception requirements, provided that the holdover personal services arrangement in on the same terms and conditions as the immediately preceding agreement.

The personal services exception requires that personal service arrangements cover "all" of the services to be furnished by the physician. The exception provides that this requirement is met if all separate arrangements between the entity and the physician (and any physician family members) incorporate each other by reference, or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for CMS's review. *See* 42 C.F.R. 411.357(d)(ii). In the preamble to the Phase III Regulations, CMS explains that the exception permits, but does not require, the use of a master list. CMS states that parties seeking protection under this exception must have a written agreement that covers all of the services to be furnished by the physician and that a master list may be used to meet this requirement. CMS warns that arrangements with family members of a physician also must be included on the master list. 72 Fed. Reg. at 51,046.

Recruitment and Retention

The Phase III Regulations make several material changes to the exceptions for physician recruitment and relocation.

One set of modifications relate to the determination of which hospitals are eligible to qualify for the relocation exception and for which locations. Significantly, the Phase III Regulations now provide alternative methods for hospitals to determine the "geographic area served by the hospital." This calculation is important because the recruitment exception only protects arrangements intended to induce a physician to relocate his/her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff. *See* 42 C.F.R. 411.357(e). Under Phase III, the geographic area served by a hospital is deemed to be the area comprised of *all* of the contiguous zip codes from which the hospital's inpatients are drawn when the hospital draws fewer than 75% of its inpatients from contiguous zones.

New under Phase III are provisions that allow hospitals located in rural areas to determine the geographic area that they serve using an alternative test that encompasses the lowest number of contiguous (or in some cases non-contiguous) zip codes from which the hospital draws 90% of its inpatients. Special provisions allow hospitals in rural areas to recruit physicians to areas outside of the hospital's geographic service if CMS determine through its advisory opinion process tat the area has a demonstrated need for a recruited physician.

In the preamble, CMS addresses several specific questions involving scenarios posed by commenters pertaining the determination of geographic service area. The first question is about how a hospital should determine its geographic service area if the contiguous zip codes proximate to the hospital account for only 69% of its inpatients but that due to the hospital's national reputation the remainder of its inpatients are drawn from distant, noncontiguous zip codes. CMS responds that, although it does not expect many hospitals to be in this situation, such a hospital under the Phase II definition of "geographic area serviced by the hospital" would be prohibited from relying on the recruitment exception. The problem is that the hospital would fail to satisfy either the original "at least 75% of inpatients" drawn from contiguous zip codes (applicable for all hospitals) or the "at least 90% of inpatients" test now available for rural hospitals. For this reason, CMS in Phase II modified the regulations to allow the hospital to include *all* of the contiguous zip codes from which inpatients are drawn when it draws fewer than 75% (or 90% for rural hospitals) from those contiguous zip codes. So, in the end, the hospital in the scenario would qualify for the recruitment exception under the Phase III Regulations. 72 Fed. Reg. at 51,050.

Another scenario involves a hospital with a zip code "hole" in the contiguous service area, resembling a donut. CMS explains that if the "hole" zip code is surrounded by contiguous zip codes and no people live in the "hole" zip code, *e.g.*, the "hole" zip code is assigned to a large office building or commercial district, then the hospital may recruit a physician to establish a practice in the "hole." CMS states that if multiple configurations containing the same number of zip codes permit the hospital to meet the applicable percent of inpatient test, (75% for all hospitals or 90% for rural hospitals), then the hospital is free to use any of the configurations. 72 Fed. Reg. at 51,050.

CMS states the hospital may use any configuration that satisfies the lowest number of zip/codes for the applicable percent of inpatients test on the date it enters into the recruitment arrangements, meaning the date on which all parties have signed the written agreement. CMS acknowledges that this may result in different geographic service areas for different arrangements. 72 Fed. Reg. at 51,050-51,051. However, CMS does not address the possibility that inpatient patterns may change during the time that a recruitment arrangement is being negotiated, such that an arrangement that met the test when the hospital developed its physician recruitment plan may not be protected by the time the final agreement with a specific recruited physician is signed.

CMS also states that the geographic service area is to be determined on a hospital-specific basis, not at the hospital system level. This may complicate the medical staff development plan implementation process for health systems comprised of more than one hospital where a recruited physician is expected to fill service needs at more than one facility — what if only one hospital meets the zip code test?

Another set of changes under the Phase III Regulations pertain to which physicians are exempt from the general requirement that the recruited physician "relocate" his/her medical practice to the geographic area served by the hospital. Residents and physicians who have been in practice 1 year or less continue to be exempt. CMS states in the preamble that a "residency" includes all training, including post-residency fellowships. 72 Fed. Reg. at 51, 051.

Also exempt now are physicians who for 2 immediately prior years were employed full-time by a federal or state bureau of prisons, the Department of Defense, Department of Veterans Affairs or facilities of the Indian Health Service, provided that such physician did not maintain a separate private practice in addition to such full-time employment. Also exempt are physicians for whom CMS has issued an advisory opinion finding that such physician did not have an established medical practice comprised of a significant number of patients who are or could become patients of the recruiting hospital. CMS clarifies that for all physicians subject to the relocation requirement, the physician must relocate his/her practice from an area outside the geographic service area to a location inside the geographic service area and either move his/her medical practice at least 25 miles or have a new medical practice that derives at least 75% of its revenues from professional services furnished to patients, including hospital inpatients, not seen or treated by the physician at his/her prior medical practice site during the preceding 3 years measured on an annual basis, whether calendar or fiscal. In the preamble, CMS re-affirms its position that physicians already on a hospital's medical staff, even courtesy privileges, are not eligible for recruitment assistance under the exception. 72 Fed. Reg. at 51, 048.

The Phase III Regulations change how income guarantees and practice restrictions may be structured when the recruited physician joins an existing physician group. The Phase III Regulations permit a more generous income guaranty under certain circumstances in the case of a physician who is recruited to replace a deceased, retiring or relocating physician. The Phase III Regulations also permit group practices to impose certain practice restrictions on recruited physicians that do not "unreasonably restrict" the physician's ability to practice medicine in the geographic area served by the hospital. CMS specifically cites with favor "depending on the circumstances" factors such as headhunter fees, travel expenses and moving expense associated with the recruitment, and employee benefits, taxes and professional fees attributable to hiring the recruited physician as among the potential "additional incremental costs" that could be allocated by a group to a recruited physician. Separately, "actual costs incurred by the . . .

physician practice in recruiting the physician . . . " that are not passed on the recruited physician refers to costs incurred in the recruiting of the physician, not costs incurred after the physician has joined the group. Examples include actual costs of headhunter fees, air fare, hotel, meals, and other cost associated with visits by the recruited physician and his/her family to the relevant geographic area, also moving expenses, telephone calls and tail malpractice insurance covering the physicians' prior practice. 72 Fed. Reg. at 51,049.

CMS makes an interesting comment in the preamble that it recognizes that parties to recruitment arrangements "may anticipate some referrals" from the recruited physician. CMS states that the "volume or value" condition prohibits the amount of assistance payable to a physician or group practice from taking into account in any manner the volume or value of past or anticipated referrals to the hospital. For example, CMS says, the unconditional payment of actual moving expenses would not take into account the volume or value of referrals. CMS also confirms that hospitals may impose "reasonable credentialing

restrictions" on physicians when they compete with the recruiting hospital, but such restrictions may not take into account the volume or value of referrals. 72 Fed. Reg. at 51,049.

CMS also addresses that recruitment payments from a hospital to a non-physician practitioner would not implicate the self-referral law, unless the non-practitioner "serves as a conduit" for physician referrals or is an immediate family member of a referring physician, yet does not provide any guidance on how to determine when a non-physician practitioner "serves as a conduit." 72 Fed. Reg. at 51,049.

CMS also states in the preamble that nothing in the regulations precludes a hospital from requiring a physician practice to repay any monies advanced to the group on behalf of the recruited physician if the physician does not fulfill his/her community services requirement. However, CMS warns, if requiring the physician practice to make such repayment is sued to "shield" the recruited physician from any real liability for failure to fulfill his/her service obligation, the parties would be "at significant risk of noncompliance" with the fraud and abuse laws. 72 Fed. Reg. at 51,051.

Another material change to the recruitment exception regulations is that they now apply to federally qualified health centers and rural health clinics, as well as hospitals.

The Phase III regulations also allow a group to allocate aggregate overhead and other expenses, not to exceed 20% of aggregate costs, where the recruited physician is replacing a deceased, retiring or relocating physician in an underserved area. In the alternative, the group may allocate the actual additional incremental costs attributable to the recruited physicians as provided under Phase II.

A physician who merely "co-locates" with a physician practice, for example, by leasing office space from the group, are not eligible under the exception. 72 Fed. Reg. 51,053. CMS clarifies that the exception applies only where the physician joins the group by becoming a member of the group or a physician in the group or equivalent (for groups that are not group practices as defined). Arrangements where a recruited physician uses funds from a hospital to pay inflated rental payments to a group practice would not be protected, CMS says, nor would recruitment arrangements used by a hospital to provide remuneration indirectly to the physician practice for example by arranging for the recruited physician to co-locate with but not join the existing group and to pay inflated amounts for rent or services. 72 Fed. Reg. 51,053. Further, CMS warns, any lease or contract between the recruited physician and a group would create a financial arrangement that requires an exception, such as the exception for rental of office space.

Moreover, such lease would potentially create an indirect arrangement between the hospital and the practice's physicians who refer DHS to the hospital that needs to satisfy the exception for indirect compensation arrangements.

CMS also addresses the exception's prohibition on the group's imposing any practice restrictions on the recruited physician. CMS states in the preamble that it intended to include only such restrictions that would have a "substantial effect" on the recruited physician's ability to remain and practice medicine in the hospital's geographic service area after leaving the physician practice. CMS states that it does not consider the following restrictions as falling into the category of having a substantial effect on the recruited physician's ability to remain in the hospital's geographic service area:

- Restrictions on moonlighting
- Prohibitions on soliciting patients and/or employees of the practice
- Requiring the recruited physician to treat Medicaid and indigent patients
- Requiring that the recruited physician not use confidential or proprietary information of the practice
- Requiring the recruited physician to repay losses of his/her practice that are absorbed by the physician practice in excess of any hospital recruitment payments
- Requiring the recruited physician to pay a predetermined amount of reasonable damages, that is liquidated damages, if the physician leaves the physician practice and remains in the community. CMS remarks however, that it may consider a significant or unreasonable payment of this type to have a substantial effect on the physician's ability to remain n the area. CMS also states that any practice restrictions or conditions that do not comply with applicable state and local law run a significant risk of being considered unreasonable.

72 Fed. Reg. 51,053 – 51,054.

Finally, CMS states that there is no "grandfathering" of pre-existing recruitment arrangements. CMS refers in the Phase III preamble to its previously posted guidance regarding pre-existing physician recruitment agreements dated on July 14, 2004, which was posted on the physician self-referral website in the form of a question and answer. In the Phase III preamble, CMS says that "any arrangement that was in effect as of July 26, 2004 [the effective date of Phase II Regulations], should have been amended to comply with Phase II, whether the arrangement was in a payout period or in a forgiveness period" (72 Fed. Reg. at 51,048). This is an important statement that does not square precisely with the Q&A guidance that CMS refers to as previously posted on its website. The Q&A said that:

> . . . continuing obligations (*i.e.*, obligations for which performance is not yet required or is not yet complete) under a pre-existing recruitment arrangement must comply with the Phase II regulations as of July 26, 2004. For example, past payments under an income guarantee need not be recalculated so long as, at the time they were paid, the arrangement complied with a reasonable interpretation of the statute.

CMS Q&A Answer ID 3163 updated 9/14/2004.

The Q&A thus suggested that properly structured recruitment arrangements then in the forgiveness period need not be re-structured, provided the income subsidy previously paid was structured under a reasonable read of the statute. Now, in Phase III, CMS says the opposite — that recruitment arrangements in the forgiveness period need to be re-structured to bring them into compliance. But CMS leaves un-answered the question of how exactly parties to such an arrangement would restructure the forgiveness period obligations yet to be performed where the income subsidy had been properly structured under existing regulations. Is the forgiveness period supposed to be lengthened, shortened, or waived? If so, this could result in a windfall to the physician, clearly not what CMS intended. Is full repayment without a forgiveness period to be demanded, thereby subjecting the hospital to liability for breach of contract? If so, this would result in

the physician's having unintended significant financial liability for an arrangement that was structured in a compliant manner at the time. Plainly, CMS should re-think its latest pronouncement in this area.

Isolated Financial Transactions

The preamble to the Phase III Final Regulations clarifies certain issues relating to the use of a promissory note to secure installment payments in an isolated transaction and the applicability of the exception in the context of post-closing adjustments and actions to collect on a breach of warranty.

The Phase II Regulations provided that installment payments could qualify as isolated transactions if, among other requirements, the payments are immediately negotiable or guaranteed by a third party, are secured by a negotiable promissory note, or are subject to some other similar mechanism to ensure payment in the event of a default. The preamble to the Phase III Final Regulations clarifies that while a promissory note is one means of securing the payment of installment payments in a transaction, the promissory note does not need to be immediately negotiable in order to satisfy the requirement, thereby permitting the use of a promissory note that may, for example, only be subject to collection upon a failure to make payment of the required installment payments. 72 Fed. Reg. 51,055.

In addition, the preamble to the Phase III Final Regulations clarifies that any post-closing adjustment occurring after the expiration of the six-month period from the date of the purchase or sale transaction would be treated a separate, additional transaction that would need to satisfy the requirements of another exception. It is important to note, however, that notwithstanding such limitation on the length of the post-closing adjustment period, CMS does not view claims based upon the breach of representations or warranties in a transaction to constitute post-closing adjustments or separate transactions from the original transaction, and may occur at any time without jeopardizing the applicability of this exception to a transaction. 72 Fed. Reg. 51,055.

Payments by a Physician to an Entity

In Phase III, CMS makes no changes to the exception for payments by a physician to a laboratory for clinical laboratory services or to an entity for other items or services furnished at fair market value. This exception was modified in Phase II to apply only where no other compensation exception is available under the regulations. In Phase III, CMS now expands the scope of the fair market value exception to cover payments to an entity from a physician, as well as payments from an entity to a physician. Thus, what looks like an expansion of the regulatory exception for fair market value is actually a farther restriction on the once very broad "(e)(8)" statutory exception for payments by a physician to an entity. CMS explains that parties will need to use the fair market value exception when payments are not specifically covered by another exception, citing the example of equipment leases of less than 1 year. CMS caveats that space leases are not eligible for protection under the fair market value compensation, only under the space lease exception. 72 Fed. Reg. at 51,057.

Charitable Donations by a Physician

Phase II established an exemption to allow physicians to make *bona fide* charitable donations to a tax-exempt entity so long as the donation was not solicited in a manner that takes into account the volume or value of referrals or other business generated between the parties and the arrangement does not violate the Anti-Kickback Statute or billing or claims submission rules. CMS acknowledges that the language of

the Phase II Regulation may have implied that a donation is outside of protection of the exception if the physician merely intended it to be in exchange for past or anticipated referrals. As a result, in Phase III, CMS changed the regulatory language to state that the entity may not solicit the donation, nor may the physician offer the donation, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity. 72 Fed. Reg. at 51.057.

CMS declines to offer further guidance on the means by which hospitals may solicit charitable donations from their medical staff, stating that they were sufficiently clear in previous regulations that such donations are permissible so long as they do not take into account the volume or value of referrals or other business generated between the physician and the entity.

In response to comments that the purpose of the law was to prohibit entities from paying remuneration to physicians, not to prohibit physicians from contributing to entities, CMS states that all forms of remuneration are encompassed within the law and that they have adequately regulated the law to allow for legitimate fundraising purposes while barring those purposes that are illegitimate.

Non-Monetary Compensation

In modifying the non-monetary compensation exception, CMS has provided some flexibility to providers. The non-monetary compensation exception currently allows entities to provide physicians with non-monetary items or services up to $329 in annual value. Under Phase III, CMS now allows a physician to repay compensation in excess of the calendar year maximum where an entity has inadvertently paid in excess of the limit provided that: (i) the excess is no more than 50% of the cap and (ii) the excess is returned within 180 calendar days or the end of the calendar year, whichever is earlier. The repayment provision may be used by an entity only once every three calendar years with respect to the same physician. The Phase III rule also modifies the exception to allow for the provision of one local medical staff appreciation event for the entire medical staff outside of the regulatory limit, provided that any gifts or gratuities at the function (*e.g.*, door prizes) are subject to the cap. CMS also clarifies that the cap should be calculated on a calendar year basis and that the fair market value of any items and services provided under the exception should be applied towards the cap, and not their costs. The regulatory limits apply to each DHS entity, not to a parent health system. 72 Fed. Reg. at 51,058-51,059.

Compliance Training

Under the Phase II Regulations, CMS stated that it did not consider CME to be compliance training for purposes of protection under the compliance training exception. Instead, CMS suggested, entities should attempt to protect CME provided to physicians under the non-monetary compensation exception. In a reversal now, under the Phase III Regulations, CMS has revised the compliance training exception to provide protection for compliance training programs that involve CME credit, provided that the compliance training is the primary purpose of the program being offered. 72 Fed. Reg. at 51,061.

Indirect Compensation

In Phase III, CMS makes no substantive change to the text of the exception for indirect compensation arrangements. However, there is extensive discussion of the exception in the preamble. *See also* "stand in the shoes" discussion above.

The indirect compensation example discussed in the preamble involves a hospital contracting for outpatient radiology services with a joint venture owned by the hospital and physicians where payment is based on a percentage of collections. Because the hospital will bill and collect payment for the services, it is the entity furnishing DHS for purposes of Stark. CMS says that the joint venture relationship between the hospital and the physicians creates an indirect compensation arrangement between the hospital and the physicians that must satisfy the requirements of an exception. 72 Fed. Reg. at 51,062. This statement contrasts with CMS's prior stated view that joint ownership by two organizations in a third entity does not, alone, create a financial relationship between the two organizations. In the preamble to the Phase II Regulations, for example, CMS said that "[a]bsent unusual circumstances, common owners of an entity will not, by virtue of their common ownership, have ownership or investment interests in each other. However, an indirect compensation arrangement may arise from their common ownership . . . [because their] ownership or investment interests in a common entity count as links [in the chain of relationship] . . . " 69 Fed. Reg. at 16,061. Is CMS suggesting now that, even without taking into account any additional financial relationships that create links in a chain, joint ownership itself is a financial relationship "link" to be structured under an exception?

CMS continues in the Phase III preamble that a percentage contract as described in the example will cause the arrangement to fall outside the indirect compensation arrangements exception, if the return to the physician from the radiology joint venture takes into account in any way the physician's referrals to the hospital, whether or not those referrals involve services provided by the joint venture. 72 Fed. Reg. at 51,062. Moreover, CMS continues, a second indirect compensation arrangement exists between the hospital and the physicians, created by virtue of the ownership interests that does not meet an ownership exception (thereby creating a compensation arrangement) in the chain of relationships that runs: hospital-radiology venture-physicians.

This looks like a new position taken by CMS – that ownership interests that are not otherwise exempt should be treated as compensation arrangements for purposes of analysis. CMS says "this arrangement" — *i.e.*, the "second" indirect relationship that it identifies, also needs to satisfy their requirements of the indirect compensation arrangements exception. CMS continues that with respect to the second indirect compensation arrangement, the inquiry would be whether the compensation under the

percentage contract between the hospital and the radiology venture (the compensation arrangement nearest the referring physician) is fair market value not taking into account the volume or value of referrals or other business generated by the referring physician. CMS notes that the indirect compensation arrangements exception requires that the compensation "received" by the referring physician is fair market value for services and items provided. CMS says that a compensation arrangement based on a percentage of collections may not, depending on how the actual collections progressed, result in fair market value received by the referring physician. 72 Fed. Reg. at 51,062-51,063. CMS does not seem to take into consideration the possibility that a percentage arrangement, where it is a market supported methodology, should be protected.

This position also follows CMS's proposal in the CY2008 MPFS to expand the current definition of "entity" from only that entity which bills for DHSs to now include the entity that actually provides the DHS in an "under arrangements" relationship. As set forth in our comments to CMS, we have taken the position that this proposed interpretation of the Stark Law contradicts the position taken in the Phase I

Regulations in which CMS stated that it "would treat 'under arrangements' financial arrangements between hospitals and physician-owned entities as compensation and not ownership relationships." CMS further stated in 2001 that it would not interpret the statute to consider "under arrangements" to be "ownership interests" because to do so, given the high volume of these arrangements, would "disrupt patient care" and that "*bona fide* "under arrangement" relationships could easily be structured to comply with the personal services arrangement exception, or, in some cases, the fair market value exception" and that there was precedent in the statute for treating them as compensation. 66 Fed. Reg. at 942.

Open Issues Despite Issuance of Three Regulatory Phases

Application of Stark to State Medicaid Programs

In the preamble to the Phase II Regulations, CMS stated that although it had intended to address the application of the Stark Law to referrals for Medicaid covered services, CMS was "reserving the Medicaid issue for a future rulemaking." 69 Fed. Reg. at 16,055. However, conspicuously not addressed in the Phase III Regulations is any mention by CMS of how it intends to apply the Stark Law to referrals for Medicaid covered services.

For purposes of background, the Stark Law itself at 42 USC 1395nn only applies to referrals of patients to entities for designated health services covered under the Medicare program by physicians who have a financial relationship with such entities (unless an exception applies). However, in 1993, the Medicaid statute was amended to prohibit federal financial participation to state where designated health services are furnished to an individual based on a physician referral that would result in a denial of payment for the services under the Medicare program if Medicare covered the services to the same extent, and under the same terms and conditions, as the service is covered under the Medicaid program. *See* 42 U.S.C. §1396b(s). Nevertheless, the states still have not received guidance on how the Stark Law will be applied to the provision of Medicaid services, especially as each state may cover different "designated health services" in different ways and to different extents. Consequently, questions arise such as:

- When (and in what context) will CMS issue guidance to the states on the application of Stark to the state's federal financial participation requirements?
- Do states need to include in the their State Plan a description of how it intends to comply with the requirements under the Stark Law?
- If a state covers a designated health service differently than the Medicare program (*e.g.*, the state considers more outpatient prescription drugs than may be covered under Medicare Parts A and B), is federal financial participation dollars at jeopardy only with respect to referrals by physicians for outpatient prescription drugs that Medicare would cover or for all outpatient prescription drugs the state Medicaid program covers?

Advisory Opinions

Another practical issue needing to be addressed by CMS is how it intends to begin to issue advisory opinions concerning the application of the Stark Law. In the Phase III Regulations, CMS removed the

sunset provision that had applied to CMS's authority to issue advisory opinions based on the indefinite extension of this authority under the SCHIP Benefits and Improvements Act of 2000.[5]

However, in contrast to the numerous advisory opinion that have been issued by the Office of Inspector General under the AKS and other fraud and abuse provisions and except for a dozen or so advisory opinions that were issued by CMS from 2004-2005 interpreting whether hospitals were "under development" for purposes of the specialty hospital moratorium, there has been a dearth of advisory opinions interpreting the Stark Law. With the issuance of Phase III, a number of questions arise: Will CMS begin responding to requests for advisory opinions that have largely remained unanswered over the years? As is clear from the resources required of the OIG to issue advisory opinions, has CMS received funding to hire additional staff who will be responsible for drafting and responding to requests for advisory opinions?

In fact, the first advisory opinion since completion of Phase III rulemaking was posted on October 3, 2007 (CMS-A0-2007-01) and considered an issue created by a Phase II change in the physician recruitment rules, opining that the repayment terms in a recruitment arrangement between a hospital and a physician could not be amended without violating the Stark Law.

In this Advisory Opinion, the facts included a hospital and a physician that had entered into a recruitment agreement in April 2004, providing financial assistance to induce the physician to relocate his practice and join a group in the hospital's geographic service area. The assistance came in the form of three loans: a moving expense loan; a $25,000 loan if the physician furnished services in the service area during April and part of May 2004; and an income guarantee loan. All three loans were secured by a promissory note which would be forgiven if the physician remained in the service area for a period after the term of the income guarantee loan.

In the original recruitment agreement, the income guarantee loan provided that the hospital would guarantee a certain amount of monthly revenue, plus an amount for actual start-up and operating expenses directly attributable to the physician's medical practice, less the amount collected which was attributable to the physician's performance of services. Although not required by Stark, the recruitment agreement further specified that if the monthly amounts generated by the physician exceeded the sum of the guaranteed revenue and physician expenses in any month, the physician would remit the excess amount to the hospital (the "Excess Receipts Provision").

Shortly after this agreement was executed, Stark's Phase II regulations became effective, requiring that an income guarantee offered by a hospital to a physician joining a medical group could only include amounts for practice expenses that are actual additional incremental costs attributable to the recruited physician.[6] Consequently, the hospital, physician and medical group modified the original agreement to change the definition of physician expenses from all expenses attributable to the physician's practice to actual additional incremental costs. As a result, under the amended agreement, the physician could be

[5] *See* SCHIP Benefits and Improvements Act of 2000 Pub. L. 106-554 codified at 42 U.S.C. § 1395nn(g)(6); s*ee also* 42 C.F.R. § 411.370 et seq.

[6] Phase III added a further refinement of permissible physician expenses: when a physician with an income guarantee is employed by a group, and he is replacing a deceased, retired or relocating physician within the group, the expenses attributable to the recruited physician may be based on a per capita allocation of the practice's aggregate overhead and other expenses, not to exceed 20% of the practice's aggregate costs.

obligated to repay the hospital a larger sum each month under the Excess Receipts Provision. In its request for an advisory opinion, the hospital sought approval for deleting the Excess Receipts Provision from the recruitment agreement.

Perhaps not surprisingly, CMS declined to approve such deletion, noting that the purpose of the physician recruitment exception is to facilitate the hospital's recruitment of needed physicians; in CMS' view, offering the physician more favorable terms after he has already relocated could not be an inducement for the relocation.

Interestingly, the advisory opinion does not disclose whether the original recruitment agreement contained any language allowing the parties to modify its terms based on unforeseen circumstances, such as the change in law underlying the facts at issue. If so, it would seem that an argument could be made that the negotiated ability to modify the agreement was part of the original inducement, and therefore the requested deletion should be permitted. Clarification of CMS' view on this nuance will have to wait until further guidance is forthcoming.

Limitation on Billing and Claims Submission

CMS addresses the interesting question of how long a DHS entity is precluded from submitting claims for services referred by a physician where the parties have a financial relationship that fails to meet an exception. CMS says that it is addressing the billing and claims submission prohibition, which is reflected in the statute without limitation, in another rulemaking (72 Fed. Reg. at 51,025).

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If you would like additional information regarding this topic, please contact: Jana Kolarik Anderson at 202/861-1804 or jkolarik@ebglaw.com; Jason Christ at 202/8611828 or jchrist@ebglaw.com; Marci Handler at 202/861-1382 or mhandler@ebglaw.com; David Matyas at 202/861-1833 or dmatyas@ebglaw.com; Elizabeth Murphy at 202/861-1834 or emurphy@ebglaw.com; Chris Panczner at 212/351-4793 or cpanczner@ebglaw.com; Carol Saul at 404/923-9069 or csaul@ebglaw.com; Carrie Valiant at 202/861-1857 or cvaliant@ebglaw.com or or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green's Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

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Amy Simmons
Marketing & Recruitment Manager
Health Care & Life Sciences Practice
Epstein Becker & Green, P.C.
1227 25th St., NW, Suite 700
Washington, DC 20037
phone (202) 861-1811 — fax (202) 296-2882
asimmons@ebglaw.com

Name: _____ Title: _____

Company/Firm/Organization: _____

Street address: _____

City: _____ State: _____ Zip Code: _____ _____

Phone number: _____ Fax number: _____ _____

Internet E-mail address: _____ _____

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