SPECIAL ALERT

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Where "The Agony and the Ecstasy" Meets "Back to the Future":

Proposed Modifications to the Stark Law Regulations Included in FY 2009 Hospital Inpatient Prospective Payment Rule

This EBG Client Alert is the third in a series prepared by EBG discussing major Stark Law regulatory issuances. See "The 'Agony' and the 'Ecstasy" Continues with Issuance of Final Phase III Stark Regulations" copyright 2007; see also "The Agony and the Ecstasy of the Final Stark II Regulations" copyright 2001.[1]

On April 14, 2008, the Center for Medicare and Medicaid Services ("CMS") posted the FY 2009 Hospital Inpatient Prospective Payment System Proposed Rule ("2009 IPPS Proposed Rule"), which was then published in the April 30, 2008 Federal Register. In addition to the wide range of payment issues addressed in this proposed rule, CMS also has proposed a number of significant changes to the regulations affecting physician financial relationships under the Stark Law.

Substantively, the key Stark Law issues addressed in the 2009 IPPS Proposed Rule include:

- the "stand in the shoes" concept under indirect arrangements,
- the period of payment disallowance following a Stark Law violation,
- a renewed proposal to require hospitals to disclose the full extent of their physician financial relationships, along with a "information collection" form designed to accomplish the disclosure;
- a request for public comments on whether CMS should develop a specific exception for gainsharing arrangements, and
- whether the public believes that the Stark Law should be broadened to also apply to physician owned device or implant companies.

CMS's publication of Stark-related proposals in the annual hospital payment regulations alone warrants comment. This is yet another example of the piecemeal and hurried approach CMS recently

[1] Copies of these and other EBG Client Alerts are available upon request. See contact information at the end of this publication.

has adopted to issuing regulations under the Stark Law, an approach that fails to effectively put all stakeholders on notice of the new rules. In contrast to previous practice in which Stark regulations were a separate rulemaking devoted exclusively to the self-referral law, over the last couple of years, CMS has proposed significant changes to the self-referral regulations inserted within other voluminous CMS issuances geared toward a subset of health care stakeholders. Last year, CMS proposed changes to the Stark regulations as part of the 2008 Medicare Physician Fee Schedule Proposed Rule ("2008 MPFS Proposed Rule"). Now, CMS has included proposed changes to the Stark regulations in this 2008 IPPS Proposed Rule. This is problematic and challenging for health care organizations seeking to remain compliant, or to have a meaningful opportunity to comment on important regulatory developments. It is especially troubling for health care organizations who furnish designated health services, but are not physicians or hospitals. CMS instead should return to a consistent approach to modifying the Stark regulations so that all potentially affected health care organizations can participate in the notice and comment process.

This is especially of concern where, as here, CMS is proposing such a fundamental alteration in Stark Law analysis in several significant areas — in particular, its stand in the shoes expansion as well as its "back to the future" reopening of the battle hard-fought and settled many Stark phases ago that Stark does not apply to manufacturers of items that become DHS when furnished by a participating supplier or provider, such as drugs or devices. If finalized, these interpretations would result in an expansion of the Stark Law far beyond the designated health services (DHS) enumerated by Congress, and with relatively narrow exceptions.

In an area where the objective is to achieve "bright lines" of what is permissible and what is not, and to promote compliance with those rules, it is virtually impossible to achieve that goal with complicated analyses that change fundamentally every couple of years. Instead of adopting new concepts like "stand in the shoes," CMS should consider issuing more clear guidance regarding the scope and mechanics of its relatively recent concept of "indirect financial relationships" and the "indirect" exception.

One bright spot is a proposal to allow organizations subject to Stark through indirect means the ability not have "stand in the shoes" apply if the direct relationship with the physician meets one of the "direct" exceptions for physician compensation. This is also a "back to the future" approach that was used, in somewhat modified form, to protect arrangements prior to CMS's mandate to use the "indirect" analysis. Also proposed is another "back to the future" alternative exception for "mission support" payments in integrated delivery systems, which was long ago proposed by the health care community but rejected by CMS. Despite these helpful steps in the right direction, and which are necessary even if CMS declines to expand the proposed reach of Stark, CMS continues to take an extremely narrow approach to Stark exceptions, proposing "alternatives," only one of which can be adopted. A better approach would be to adopt a range of acceptable alternative exceptions, including both of these exceptions and more, in recognition that there is no single "one-size-fits-all" exception that can cover the full range of complex structures in health care warranting protection.

CMS will be accepting comments concerning these proposed regulations until June 13, 2008. Given the importance of these proposed provisions, we strongly encourage providers to take advantage of this opportunity to submit comments to CMS before the deadline.

Background of the Stark Law and Its Regulatory History

By way of background, in 1989, Congress adopted the "Stark I" statute applicable to entities providing Medicare-covered clinical laboratory services, which became effective January 1, 1992. 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" ("DHS") that included not only clinical laboratory services, but also to 10 other types of services: physical therapy services; occupational therapy services; radiology (including magnetic resonance imaging, computerized axial tomography scans, 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. The Stark Law applies to referrals from a physician to an entity that provides any of these DHS if the physician has a direct or indirect financial relationship, whether through ownership or compensation arrangements, with the entity. Only arrangements that satisfy a specific enumerated exception are protected.

Two years later, on August 14, 1995, CMS published the first set of 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 proposed a second set of final Stark Regulations (the "Phase II Proposed Regulations").

On January 4, 2001, almost three years to the day after the Phase II Proposed Regulations were issued, CMS published in the Federal Register the first of several phases of final Stark II Regulations (the "Phase I Regulations"). Then, on March 26, 2004, CMS published a second phase of Stark II regulations (the "Phase II Regulations") as an interim final rule with comment period. Next, on September 5, 2007, CMS published the third phase of final Stark II regulations (the "Phase III Regulations"), with an effective date 90 days following publication in the Federal Register. In the interim, CMS published proposed 2008 Medicare Physician Fee Schedule regulations (the "2008 Proposed MPFS"), which surprised the industry by including a number of proposed changes to the Stark provisions. In the end, when the final 2008 MPFS was issued, CMS largely left out the Stark-related proposals from the 2008 Proposed MPFS. Now, in the FY 2009 IPPS Proposed Rule, CMS has proposed a number of additional changes to the Stark provisions.

CMS Attempts to Broaden the Scope of the Stark Law

In the Phase II Regulations, CMS introduced a new exception for "indirect compensation arrangements," which many in the industry believed was an appropriate, albeit unduly complicated, vehicle for protecting arrangements that either fell outside of Stark or should be excepted from Stark. In the Phase III Regulations, CMS expressed concern that industry representatives were taking the position under the indirect compensation provisions that arrangements were outside the ambit of the statute, taking advantage of an "unintended loophole" in the regulations.[2]

Instead of simply issuing a clarification in the Phase III Regulations to eliminate the loophole, CMS added a whole new "stand in the shoes" principle, whereby a physician is treated the same as his/her physician organization ("PO") for purposes of determining whether a financial arrangement exists with a DHS entity. In the 2008 Proposed MPFS, CMS went even further, proposing that DHS entities also stand in

[2] 2 Fed. Reg. at 51028 (Sept. 5, 2007).

the shoes of any entity that such DHS provider owns or controls. These principles result in a collapsing of the number of financial arrangements in a string of arrangements between a referring physicians and a DHS entity, increasing the likelihood that an arrangement is subject to Stark and that a "direct" financial relationship exception must be satisfied.

In light of the far reaching impact of this new analytical concept, especially on academic medical centers, many of which came to rely on "indirect" concepts instead of the difficult-to-satisfy academic medical center exception, CMS delayed the effective date of the "stand in the shoes" analysis as it applied to certain academic medical centers and integrated health care systems until December 4, 2008.[3]

Most recently, in the 2009 IPPS Proposed Rule, CMS revisits both the physician and DHS entity "stand in the shoes" principles and proposes modifications to both. As described below, these new proposals only add unnecessary complexity and additional layers of analysis. If the Stark regulations are truly intended to represent "bright line" tests, these proposals regarding physician and entity "stand in the shoes" should be abandoned in favor of a more straightforward approach, returning to the established rules on indirect financial arrangements, and issuing only such minor clarifications as are absolutely necessary to close any unintended loopholes.

Physicians "Stand In The Shoes" Of Their Physician Organizations

The Phase II Regulations dictated that financial arrangements running between a chain of entities with a DHS entity at one end and a referring physician at the other end must be analyzed for whether there is an "indirect compensation arrangement" between the parties. If yes, then the analysis turns to whether the arrangement qualifies for protection under the exception for indirect compensation arrangements. *See* 42 C.F.R. § 411.354(c)(2); 42 C.F.R. § 411.357(p). In short, only if the physician receives compensation based in any manner on the volume or value of referrals to the DHS entity would the string of arrangements be subject to Stark. Under a technical analysis of the Phase II Regulations, therefore, arrangements where physicians are not paid based on referrals fall outside of the Stark Law altogether. With the addition of the "stand in the shoes" rules in Phase III, some arrangements that would have constituted indirect compensation arrangements became analyzed as direct compensation arrangements, and some arrangements potentially falling outside of the Stark Law were drawn back within the statute's reach.

As a result of numerous comments from the health care community, CMS explains in the 2009 IPPS Proposed Rule that it is revisiting the "stand in the shoes" policy and that it is looking to achieve the goal of "simplifying the analysis of many financial arrangements" while reducing program abuse. As a result, CMS proposes two new alternatives: (1) a "multi-faceted approach" to analyzing stand in the shoes arrangements; or (2) the development of a new exception for "mission support" payments, leaving the current stand in the shoes rules intact.

Instead of "simplifying the analysis," CMS is actually further complicating the analysis by creating new exceptions to the stand in the shoes rules that are based, in large part, on already existing exceptions. In other words, CMS is proposing a re-analysis of arrangements that already satisfy an exception, but now is requiring additional layers of analysis to reach essentially the same conclusion.

[3] 2 Fed. Reg. 64161 (Nov. 15, 2007).

"Stand in the Shoes" Proposed Approach One: The "Multi-Faceted" Approach (a/k/a "If the shoe fits, wear it!")

In the 2009 IPPS Proposed Rule, CMS proposes to modify the "stand in the shoes" rules by making them inapplicable in situations where a physician's arrangement with a PO meets one of the Stark Law exceptions for *bona fide* employment (42 C.F.R. § 411.357(c)), personal services arrangements (42 C.F.R § 411.357(d)), or fair market value ("FMV") compensation (42 C.F.R § 411.357(d)). CMS says that arrangements that meet any of these exceptions would be consistent with fair market value by design and not determined in a manner that takes into account directly or indirectly the volume or value of referrals by the physician to the physician organization. CMS also proposes that the stand in the shoes analysis would not apply to arrangements protected by the AMC exception or to AMC arrangements involving GME services, both welcome clarifications.

While these proposals to limit the applicability of the "stand in the shoes" rules are helpful, they do not go nearly far enough. Specifically, a technical analysis of a physician's arrangement with his/her physician organization cannot be the only means of protecting the legality of the physician's referrals to an unaffiliated DHS entity, *e.g.* a hospital. This would require the hospital to ensure that the physician's relationship with the PO remains in compliance with Stark during all times that the physician refers to the hospital. Hospitals cannot possibly accomplish this level of oversight of an independent physician group. Even if the hospital negotiates a Stark Law compliance obligation into its contract with the PO that dictates conditions for the PO's private arrangements with its physicians, it is far from clear that this will be sufficient for Stark Law compliance purposes. Moreover, many POs rely on the compensation provisions of the group practice definition, rather than the employment or personal services exceptions, to protect their physician compensation. Any "stand in the shoes" exception would have to take this alternative exception into account.

Perhaps compliance with one of the three exceptions cited by CMS at the physician/PO relationship level could be a "safe harbor" for analyzing the physician's referrals to the DHS entity, but not a requirement for compliance at the direct relationship level. The indirect compensation rules already in existence address the issues that CMS is concerned about, namely, whether the hospital arrangement is somehow a payment to the physician for referrals.

CMS's bottom line should be, as it is under the current indirect analysis, that if the physician is not receiving compensation that varies with the volume or value of referrals to the DHS entity, then the referrals should be allowed because they do not violate (and may not even trigger) Stark. This is true regardless of whether the physician's arrangement with the PO also is in compliance with a Stark exception. Thus, for example, a physician whose group practice compensation is not paid based on hospital referrals should be allowed to refer to a hospital with which the group has a compensation arrangement, even if the physician's personal services arrangement with an independent physician group has expired and not been renewed in writing. In this scenario, although the physician's arrangement with the PO has become technically non-compliant, the physician should not be prohibited from referring to hospital because the hospital is not in control of the physician's arrangement with the group and because, at bottom, the expired contract at the PO level does not have any relevance to the hospital's relationship with the physician group.

A more straightforward approach would be to modify the indirect compensation arrangement rules to allow parties either to show that (a) the physician/PO arrangement meets an exception or (b) the DHS entity

payments to the PO are FMV for services and are not related to volume or value of referrals. Under this approach, the hospital retains the ability to control its compliance risks directly, by structuring FMV contracts within its own compliance program, without having to oversee the compliance program activities by independent POs. Or if the physicians want to ensure compliance through their PO, they can do it that way instead, or in addition. These rules would protect arrangements where the physician and PO satisfy the in-office ancillary exception (and its associated group practice definition and compensation provisions).

This would be a full-fledged version of CMS's more abbreviated "back to the future" approach, because it reflects the analysis that was done prior to the issuance of Stark II regulations mandating the indirect analysis. In those earlier days, under the prior "break the chain" approach, if the financial relationship between the DHS entity and PO satisfied an exception, it "broke the chain" and no further analysis was required. Alternatively, if the financial relationship between the physician and PO was protected, that also "broke the chain" and no further analysis of any other link in the chain was necessary. This old approach worked well — tark was presumed to apply, and the "cutesy" approaches that CMS now criticizes where parties argued that Stark does apply didn't occur — yet exceptions were available to protect most relationships deserving of protection. The difference now is that CMS is proposing an application of Stark that is far broader than ever before, with a series of analytically complicated exceptions that are not nearly sufficient to encompass all that warrants protection, but yet are proposed as "alternatives."

CMS also inexplicably suggests that exclusive arrangements trigger application of the Stark Law by "taking into account" volume or value of referrals. This suggests that arrangements where there is no compensation at all between the physician group and the hospital — *i.e.*, where the physician or physician group bills third party payors directly — would nonetheless trigger Stark simply because there is exclusivity between the parties. This is an overly broad reading of the statutory trigger that there be a "financial relationship" between the parties. Many exclusive arrangements are entered into by hospitals and their medical staffs to ensure quality and consistent coverage for needed services, *e.g.*, emergency room services, anesthesiology, pathology, radiology. The mere fact of an exclusive relationship has no bearing on whether the arrangement "takes into account" volume or value of referrals. Exclusivity is not the test for whether an arrangement implicates Stark.

CMS asks for public comments on how it can ensure that the full range of potentially abusive arrangements are addressed — the answer that CMS should re-start its process for issuing timely and meaningful advisory opinions. The mechanism for addressing these types of issues has already been created by Congress; it just needs to be implemented by CMS. While sub-regulatory guidance or posted FAQs are helpful, they cannot be the sole mechanisms available for parties that seek guaranteed protection. If CMS truly wants a meaningful process for resolving Stark issues, it needs to invest in the requisite advisory opinion process so that it, the relevant regulatory agency, can opine on the real life questions that arise and it can provide binding answers on particular arrangements, beyond the cumbersome rulemaking process.

"Stand in the Shoes" Proposed Approach Two: Development of a Mission Support Payments Exception (a/k/a "Put on your dancing shoes!")

The second approach proposed by CMS is to leave the stand in the shoes rules as currently in effect, but create a new exception for payments that do not pose a risk of program or patient abuse, such as "mission support" payments. CMS asks for public comments on whether such an exception should be limited to

"mission support" payments, whether other specific types of compensation should be eligible for protection, the types of parties able to qualify and the conditions that should be required for protection. CMS also solicits comments on how to define an "integrated delivery system" ("IDS") that could qualify for protection under the new exception.

This alternative proposal also falls under the category of "back to the future" because it is the kind of exception that the health care community was looking for years ago when integrated delivery systems first began to proliferate. Any system comprised primarily of non-profit tax-exempt organizations engaged in health care and any wholly owned subsidiaries and affiliates that are not physician owned (even if the entities are for profit or not tax-exempt) should be protected. This should apply to situations in which physicians may have nominal ownership of the entity (with none of the usual attributes of ownership) in order to satisfy state corporate practice of medicine restrictions. Any funds transferred among these family of entities do not create Stark Law financial arrangements. The Stark Law compliance issues only arise in connection with specific payments to physicians from any entity within the system, and that is where the analysis of potential exceptions should attach.

Thus, the two "alternative" approaches discussed by CMS should not mutually exclusive, nor should they be adopted only in connection with an expansion of the stand in the shoes concept. Any expansion of stand in the shoes should be eliminated. Both a "payment of FMV at any level" (a/k/a "break the chain") rule and a "mission support/IDS" exception should be adopted as additional exceptions to the Stark Law, as discussed above, as both exceptions have been needed for over a decade irrespective of any "stand in the shoes" approach. These modifications should occur along with any necessary clarifications to the indirect analysis necessary to avoid any unanticipated loopholes in CMS's indirect analysis framework.

DHS Entity "Stand in the Shoes" (a/k/a "Waiting for the other shoe to drop")

The "entity" stand in the shoes proposal first appeared last summer as part of the 2008 Proposed MPFS. Under this analysis, if the DHS entity "owns or controls" another DHS entity that has an arrangement with a physician, the first DHS entity would be deemed to stand in the shoes of the second DHS entity and have an compensation arrangement with the physician. The 2009 IPPS Proposed Rule would narrow this proposal to only DHS entities with 100% ownership interests in a second DHS entity. CMS is seeking public comments on whether this should apply to entities in which there is less than 100% ownership interest, and if it should apply to entities under the "control" of a DHS entity.

The example used by CMS is a home health agency, which is itself a DHS. Does this mean that CMS would expect a "double" Stark exception where stand in the shoes is triggered (that is, a "direct" exception at the hospital-HHA level, and another "direct" exception at the HHA-physician level? This is regulatory over-kill.

Not addressed at all are situations in which the hospital's ownership is of a non-DHS, such as a property company or ASC. There, again, CMS appears to bumping up against the limits of its statutory authority, applying the Stark Law to areas far beyond the enumerated designated health services. CMS cannot possibly mean that a physician who holds an ownership interest in a joint venture non-DHS entity along with a hospital will be deemed to have a direct financial relationship with the hospital to which no ownership

exception exists to protect it. Without carefully crafted limits to Stark Law application, the result could be an unintended prohibition of physician financial relationships with non-DHS entities.

Similarly, CMS's proposed expansion from ownership and compensation to "control" appears to be beyond CMS's statutory authority as reflected in the Stark Law. The only financial relationships specified in the statute are "ownership" and "compensation arrangements." Ownership or compensation is clearly a prerequisite to trigger application of the Stark Law.

In any event, we fail to understand why the existing indirect analysis and exception (if need be, clarified to avoid unanticipated loopholes) is insufficient for CMS's purposes. Certainly either the indirect analysis as clarified by CMS, or "break the chain at any level" analysis should suffice. At a minimum, if adopted stand in the shoes should apply only where one entity owns 100% of the interest in a second entity.

Physician Owned Implant and Medical Device Companies

CMS asks for public comment on whether the Stark Law should apply to physician- owned implant and medical device companies ("POCs"). CMS is specifically concerned that a physician's financial relationships with an implant and medical device company could raise quality and over-utilization concerns, and encourage an anti-competitive environment. As early as 2001, CMS recognized that manufacturers should not be considered entities that furnish DHS:

We agree that, in most cases, drug manufacturers are not entities that furnish DHS to patients for purposes of [the Stark Law], and therefore,, the ordering, dispensing, or prescribing of drugs would not constitute a referral to the manufacturer of the drugs.

CMS then explained that, if a manufacturer owns an entity that in fact does bill the Medicare program for services, then it is possible that the Stark Law would be implicated. Although at the time, CMS's comment was specifically directed at physicians having financial relationships with pharmaceutical manufacturers, there is no reason why the analysis should be any different for other types of manufacturers.

Consequently, if CMS were to take the position that a manufacturer is, in fact, a designated health services entity, then CMS would be expanding the breadth of the statute beyond its regulatory authority. The statute provides that if a physician has a financial relationship with an entity, then the physician may not "make a referral to the entity for the furnishing of designated health services …" ***and*** "the entity may not present or cause to be presented a claim" to the Medicare program. It is difficult, if not impossible, to argue that a manufacturer constitutes an entity that either "presents" or "causes to be presented" a claim for the designated health service.

To the extent CMS is concerned with the appropriateness of certain of these arrangements, there are other regulatory provisions (*e.g.*, the anti-kickback statute) which have been designed to address other types of improper financial relationships.

Disclosure Financial Relationship Report

The Stark Law requires that any entity that provides items or services for which payment may be made under Medicare must submit to CMS certain information about such entity's financial relationship with physicians under time periods prescribed by the entity's Medicare carrier. In 2004, as part of the Phase II Final Regulations, CMS waived all reporting requirements for designated health service entities providing

less than twenty Part A and B services during a calendar year. Moreover, CMS decided not to require regular submission of information of other providers, but instead only require information to be submitted upon request by CMS.

As part of the Deficit Reduction Act of 2005, Congress required the Secretary of the Department of Health and Human Services to develop a strategic and implementing plan to address certain issues relating to physician-owned specialty hospitals. In preparing its report, CMS sent a voluntary survey to 130 specialty hospitals and 220 competitor hospital which sought information regarding, among other things, the hospitals ownership and investment relationships and their compensation arrangements with physicians. Then, in its Final Report to Congress, CMS stated that it would require all hospitals to provide information on a periodic basis concerning the investment interests and compensation arrangements with physicians.

As a result, in 2007, CMS began its initiative to implement a survey to investigate the investment/ownership and compensation arrangements between physicians and hospitals to determine whether they are in compliance with the Stark Law and implementing regulations. This survey — entitled the "Disclosure of Financial Relationships Report" ("DFRR") — was designed to be a mandatory survey for 500 hospitals selected by CMS. The extensive worksheet contains 8 worksheets and covers direct and indirect physician investment and ownership in hospital, payments to the hospital by physician ownerships, a listing of each rental, personal service and recruitment arrangement between a hospital and physicians, and a series of questions targeting information on other types of compensation arrangements, including non-monetary compensation or medical staff incidental benefits that exceeded published limits and charitable donations by a physician to a hospital. The survey is to be completed, certified by a hospital officer and submitted to CMS within 60 days. Technically, the hospital could face penalties of $10,000 per day for late responses under civil monetary penalty provisions.[4] However, according to the preamble to the propose regulation, CMS is unlikely to invoke this authority and likely will work with the entities to comply with the reporting requirements, even granting extensions for 'good cause" shown.[5]

Under the Paperwork Reduction Act, CMS was required to obtain clearance from the Office of Management and Budget ("OMB") prior to sending out the survey. Although the DFRR was under review by OMB for several months, on April 10, 2008, OMB reported that CMS had withdrawn its request for clearance of the DFRR survey. CMS (just a few weeks later) re-introduced the form as part of the 2009 IPPS Proposed Rule.

As part of the 2009 IPPS proposed rule, CMS is soliciting comments on the following areas of the Disclosure Financial Relationship Report (DFRR):

- whether the collection efforts should be recurring, and, if so, on what basis (annually, etc.)
- whether CMS is collecting too much or not enough information, and whether they are collecting the correct (or incorrect) type of information;
- the amount of time it will take hospitals to complete the DFRR and the costs associated with completing the DFRR;

[4] 42 C.F.R. § 411.361(f).
[5] 73 Fed. Reg. at 23697.

- whether CMS should direct the DFRR to all hospitals and whether they should stagger the collection so that only a certain number of hospitals are surveyed each year; and
- whether hospitals, once having completed the DFRR, should send in yearly updates and report only changed information.

The title of the survey — "Disclosure of Financial Relationships Report" — is a misnomer in that it is less a "disclosure form" but more of an audit tool. The numerous hospitals that receive the request will be required to complete eight (8) separate worksheets that require the hospital to provide information about not only physician owners about each and every compensation arrangement the hospital may have with physicians (e.g., service, leases, recruitment, non-monetary compensation, incidental medical staff privileges). In addition, the hospitals are required to submit copies of every contract, and certify whether each of the relationships is Stark compliant.

Although in the original DFRR that CMS submitted to OMB, CMS estimated that it would take a hospital five (5) hours to complete, CMS later increased that estimate to six (6) hours. Now, in the 2009 IPPS Proposed Rule, CMS estimates that it will take a hospital, on average, 31 hours to complete the form and, therefore, will cost hospitals $1550 to complete (based on a $50 per hour rate for an accountant). CMS, in our view, is seriously underestimating the time and expense associated with this form. In reality and depending upon the size of the hospitals, it will take much more than 31 hours to read the form, organize the information, ensure that the arrangements are, in fact, compliant, complete the forms, and make copies of all the relevant documents to send to CMS. In addition, it is hard to believe that CMS really believes that this form could (or should) be completed by an accountant when the determination as to whether an arrangement satisfies an exception to Stark is an extremely complicated legal determination which will inevitably require numerous attorney hours (which will well exceed $50 per hour). Certification of compliance will be an especially daunting task in light of CMS's propensity to rewrite the Stark regulations every couple of years so as to completely revise the analytical framework for compliance.

We further doubt that CMS would seek to collect this quantity of information if it was simply attempting to track information, rather than audit compliance. In fact, CMS explains that the purpose of the DFRR is to collect information that would permit CMS to "analyze" the types of financial relationships involving hospitals and physicians, the structure of various compensation arrangements and "trends therein," and "potentially whether the hospitals are in compliance with the physician self-referral law and implementing regulations."[6] We question whether this latter purpose is beyond the statutory authority granted CMS. If CMS intends to move forward with a disclosure tool, it should return to the original intent of the tracking provision and adopt a far more streamlined approach. CMS also should seriously consider waiting until the various pieces of its Stark revisions are finalized and absorbed by the health care community before expecting hospitals to certify compliance with a brand new set of rules.

While CMS might attempt to argue that this disclosure requirement does not require any additional burden on the industry because hospitals must otherwise ensure that they do not violate Stark, it is very different to require an officer of the hospital to attest to the thoroughness of a report being submitted to the government whereby significant penalties could be assessed against the officer if the submission is not 100% complete and accurate.

[6] 73 Fed. Reg. at 23697.

Period of Disallowance (a/k/a "Cinderella's glass slipper")

Although in the 2008 MPFS Proposed Rule CMS did not make any proposals for prescribing the period of disallowance for noncompliant financial relationships, CMS did request public comments on this issue. As a result, EBG submitted comments to CMS and expressed our support of CMS in contemplating setting limits on the period of disallowance for Stark Law noncompliance, as well as allowing "alternative" criteria for satisfying exceptions. This is important given the onerous Stark Law penalties involved, even in the event of inadvertent Stark Law violations.

In the 2009 IPPS Proposed Rule, CMS proposes that where the reason(s) that a financial relationship does not meet any applicable exception is unrelated to the compensation (e.g., if an agreement is missing a signature), then the period for when referrals would be prohibited would run from the date a financial relationship failed to satisfy the requirements of an applicable exception until the date the relationship becomes compliant (e.g., by obtaining the missing signature). Therefore, for technical Stark violations, the referral prohibition ends when the relationship between the physician and the entity is brought into compliance with the Stark exception.

With respect to those financial relationships that do not meet an applicable exception and the reason is related to the compensation, CMS has proposed that the referral prohibition ends when the overpayment or underpayment is repaid (including interest) and the relationship otherwise fits within an exception. In the proposed regulations, CMS provides two examples. The first example is where a DHS entity provided $100 in excess nonmonetary compensation to a referring physician on February 1, the parties discovered the noncompliance on October 1 and the excess compensation was repaid on October 15. CMS states that the referrals would be prohibited in the period running from February 1 through October 15.

This example is unrealistic and assumes that the excess compensation would be repaid almost immediately upon discovery. Furthermore, CMS does not explain why good faith efforts to repay the money would not "fix" the technical violation in its entirety or at least be a factor for determining the period of non-compliance.

The second example is with respect to relationships that are non-compliant due to payment of insufficient compensation. For example, CMS provides an example in which a hospital executes a 2 year space lease with a physician a physician is to pay a fair market value rental rate of $20 per square foot in Year 1 and a CPI-U adjusted amount in Year 2. If the parties ignore the CPI-U adjustment, and the physician continues to pay the hospital at $20 per square foot (instead of say $21 per square foot), CMS states that the arrangement is out of compliance and will remain so until the physician makes up the "shortfall" ($1 per square foot per month).

Additionally, CMS states that there are other examples that are compensation-related, but there is no excess or insufficient payments that are implicated and examples where the relationship does not return to compliance. These types of arrangements generally involve a period that begins on the date the arrangement first failed to meet an exception and end on a date that involves a case by case analysis.

CMS suggests that full payback between the parties of amounts in excess of fair market value is necessary in order to end the period of non-compliance and further it will be necessary for the DHS entity to pay a multiple of referral revenue in damages to the government to resolve the remainder of the case.

However, we believe that payback between the parties should resolve the non-compliance altogether if it is truly a Stark technical non-compliance matter (as opposed to a kickback). Indeed we believe that some circumstances warrant no "period of disallowance" at all. Specifically, if the parties to an arrangement did not realize that they were in violation, they ought to be able to reconcile the arrangement to be in compliance with the exception without any period of disallowance at any time before they are alerted by the government that there is a possible violation. Physicians frequently are not aware of the far reaching implications of the Stark Law on their long-standing arrangements until they engage a compliance review which points out certain discrepancies in their longstanding practices. This may occur, for instance, in group practice compensation formulas. In such circumstances, the parties should be able to determine what permissible compensation should have been, alter the methodology on a going forward basis, and make an internal payment reconciliation with the affected physicians to achieve compliance, without violating the Stark Law for any period of time whatsoever. Such a provision would encourage health care entities to conduct frequent compliance assessments and remedy any shortfalls in compliance, and is fair and reasonable in light of the draconian and far reaching Stark Law penalties that apply.

CMS states in the proposed regulations that it has no authority to do this, but it is unclear why the general exception authority would not allow an exception of this breadth. If CMS can except certain de minimis payments and if CMS has the authority to create certain "holdover" and "temporary noncompliance" exception, it certainly can except a subset of arrangements that "fell through the cracks" where the parties took swift action to remedy the situation, including full payback between the parties. Given the draconian nature of Stark penalties (including refund of all referral revenues from the physician), a good faith attempt by the parties to remedy a mistake ought to be acknowledged in the regulations.

It also is beyond belief (and likely statutory authority) that the period of noncompliance may not end with the termination or expiration of the financial relationship if there is no repayment between the parties because the excess or shortfall may be for future referrals. The Stark Law is not intent-based, and so the period of liability should not be based on whether the payment, or lack of repayment, was intended for future referrals. It is completely unrealistic for CMS to expect individual physicians to repay potentially huge sums of money to hospitals in order to stop the clock on the hospital's non-compliance. While most hospitals would welcome having clout to seek payback from physicians, clearly this clout could not come at the expense of potentially creating a continuing Stark liability forever.

In sum, we fail to understand why there is no mechanism for simply fixing inadvertent violations without the burden and expensive of voluntary disclosure. We would recommend that the self-disclosure prerequisite be eliminated. If not, any reasonable disclosure to any governmental agency or agent should be acceptable.

Gainsharing

In the 2009 IPPS Proposed Rule, CMS requests public comment on whether there should be an exception to the Stark Law concerning "gainsharing" arrangements, which CMS defines as arrangements "under which a hospital gives physicians a share of the reduction in the hospital's costs (that is, the hospital's cost savings) attributable in part to the physician's efforts."

CMS acknowledges in the preamble that in addition to the Stark Law, there are a number of other fraud and abuse laws that are potentially implicated by these gainsharing arrangements (e.g., the anti-kickback

statute and the civil money penalty statute.) Consequently, CMS discusses in the preamble that gainsharing arrangements have been the subject of numerous OIG advisory opinions, that MedPAC has recommended that gainsharing arrangements be permitted, and that CMS has initiated a number of demonstration projects concerning gainsharing. After reviewing this history, CMS suggests that it is searching for a set of gainsharing principles that would permit physicians and hospitals to align their incentives to improve the quality of care and reduce costs without the risk of program or patient abuse. Specifically, CMS wants input on requirements and safeguards that should be included in any gainsharing exception and whether certain services, clinical protocols, or other arrangements should not qualify for the exception.

On May 5, 2008, EBG submitted a letter to OIG in response to the OIG's request for new safe harbors and special fraud alerts.[7] We urged the OIG to publish a safe harbor protecting arrangements between a hospital and its medical staff pursuant to which the medical staff physicians receive payment for participating in legitimate cost efficiencies and quality enhancement efforts at the hospital where certain program and patient protections are also in place. We submitted that OIG also has authority to issue the same regulatory provisions as an exception to the civil monetary penalties provisions and suggested that mirror language also could be adopted by CMS as a regulatory exception to the federal Stark Law, in a similar manner to the electronic prescribing/electronic health records safe harbors and Stark Law exceptions.

As we stated in our letter to OIG, in light of the significant public policy need to support carefully structured, clinically supported quality and cost-efficiency programs in hospitals, we submit that the time has come for careful consideration of an anti-kickback safe harbor and companion Stark and CMP regulatory exceptions for appropriately structured programs that include appropriate payments to physicians for their participation in gainsharing arrangements, without which such programs will not succeed. The success of governmental quality initiatives and industry pay-for-performance programs involving hospitals depends on physicians' willingness to participate in such programs, and hospitals being protected from risk of violating the various fraud and abuse laws and their onerous penalty provisions.

We proposed to the OIG, and reprint here, criteria for protecting quality initiative programs. Our proposal is based on standards adopted by the OIG in individual advisory opinions on gainsharing. It also borrows from Stark regulations governing referrals and distribution of referred ancillary service revenues by group practice physicians.

The prohibition on referrals set forth above does not apply to arrangements where:

(1) The arrangement is set out in writing and signed by the parties.

(2) The agreement covers all of the terms and provisions of the parties' arrangements.

(3) The term of the arrangement is for not less than one (1) year.

(4) The arrangement includes a compensation methodology that is set in advance as a specific formula in the agreement between the parties before the furnishing of any items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that directly takes into account the volume or value of referrals or other business generated by the referring physician.

[7] Solicitation of New Safe Harbors and Special Fraud Alerts published on December 19, 2007 at 72 Fed. Reg. 71868.

(5) The arrangement incorporates quality performance and/or cost effectiveness measures that do not mandate specific, direct reductions in length of stay, but which may direct the use of specific devices and supplies or establish protocols for cost-effective use or standardization of products.

(6) The individual physicians who participate in the arrangement receive a per capita share of the aggregate payment pool made available for participation in the measure or the cost-savings generated by the results of the measure.

(7) Payments made to individual physicians shall be adjusted to not take into account increases in value or volume of patients or services ordered or referred by each such referring physician.

(8) Physicians participating in each measure are not chosen based on the volume or value of their referrals or other business generated for the hospital.

(9) Written disclosure of the measure(s) and the physician's financial relationship with the hospital pertaining to the measure(s) is made to each patient whose care may be affected by the measure(s) prior to the furnishing of services. Any request by a patient that one or more measures not be applied to them shall be granted. In connection with measures that encourage product standardization, a protocol will be put in place that allows participating physicians to access the same selection of products as existed prior to the measure being implemented upon request.

(10) Each quality or cost-saving measure is supported by credible medical evidence that implementation of the measure will not adversely affect patient care. Adoption by CMS of a measure in conjunction with the Hospital Quality Alliance shall constitute credible medial evidence for purposes of this criterion.

(11) Each measure is clearly and separately identified in writing prior to implementation and any cost savings resulting from such measure is separately tracked and paid from any other measure.

(12) The measures shall not be disproportionately applied to Federal health care program beneficiaries.

(13) Protections shall be implemented against inappropriate reductions in service by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings will accrue to the participating physicians.

(14) Payment for any individual measure shall be reasonably limited in duration and amount, and any continuation beyond a one-year period shall take into account that payments already have been made for savings already achieved during the previous year.

(15) The hospital monitors physician compliance with these requirements and documents its audits and oversight activities and results, and takes prompt action to remove from participation any physician who fails to comply.

* * *

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