



An Analysis of Gainsharing Arrangements Under The Stark Law

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I. Introduction

Gainsharing—it is the talk of the town. Re-energized by the U.S. Department of Health and Human Services (DHHS), Office of Inspection General's (OIG's) release of six new advisory opinions approving hospital-physician cost-saving (or "gainsharing") arrangements, gainsharing is not only a topic of discussion among traditional healthcare providers, but also has piqued the interest of device manufactures, particularly with respect to perceived changes in the ability of hospitals to share with physicians cost savings generated through product standardization initiatives. In Advisory Opinions 05-01 through 05-06 (the Advisory Opinions), the OIG analyzed several similar gainsharing arrangements under §§ 1128A(b)(1) (the Civil Money Penalty (CMP) Statute) and 1128B(b) (the Anti-Kickback Statute) of the Social Security Act. The OIG concluded that the gainsharing arrangements at issue violate the CMP Statute and potentially generate "prohibited remuneration" under the Anti-Kickback Statute. Even so, the OIG determined that the benefits of the arrangements outweighed their potential for abuse and, as such, stated that it would not sanction the parties.

The OIG, however, consistently cautioned that gainsharing programs "may implicate" other federal legal authorities, most notably the federal physician self-referral law, commonly referred to as the Stark law.¹ Because the Stark law falls outside the scope of its advisory opinion authority, the OIG has not expressed an opinion as to whether the gainsharing arrangements reviewed in the Advisory Opinions implicate or violate the Stark law. The application of the Stark law cannot be ignored, however, and must be understood by hospitals, physicians, and their consultants before they pursue a gainsharing program in earnest.

This article offers a Stark law analysis of the gainsharing arrangements approved by the OIG in the Advisory Opinions, with the objective of identifying principal open

issues and potential pitfalls, and hopefully sparking a constructive, public dialogue regarding possible solutions.

II. Background

According to the OIG, while there is no fixed definition of "gainsharing," the term typically refers to an arrangement in which a hospital offers to share with certain physicians a portion of the cost savings achieved by the hospital in the provision of patient care services that are attributable, at least in part, to the efforts of the physicians.² In a July 1999 Special Advisory Bulletin, however, the OIG asserted that gainsharing arrangements violate the CMP Statute, which prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services furnished to Medicare or Medicaid beneficiaries under the physician's direct care.³ A hospital that makes and a physician who receives such a payment are each subject to civil penalties of up to \$2,000 for each beneficiary with respect to whom such payment is made.⁴ Although the OIG recognized that properly structured gainsharing arrangements may offer significant benefits (especially when there is no adverse effect on the quality of care), it concluded that the CMP Statute "clearly prohibits such arrangements."⁵

Then, in January 2001, the OIG issued Advisory Opinion 01-01 in which it approved a gainsharing arrangement between a hospital and a group of cardiac surgeons involving the surgeons' agreement to implement several cost-savings measures in connection with designated surgical procedures. While Advisory Opinion 01-01 may have caught some industry observers by surprise (given the OIG's July 1999 Special Advisory Bulletin), it was welcomed by those who believed that aligning the financial incentives of hospitals and physicians is essential to achieving meaningful hospital cost savings and feared the Special Advisory Bulletin had put an end to the development of gainsharing

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arrangements. Now, with the OIG's release of the six Advisory Opinions, the interest in exploring gainsharing programs has been rekindled on a nationwide basis.

A. OIG Advisory Opinion Authority

As part of its stock advisory opinion language, the OIG includes a disclaimer that an analysis of the arrangement under the Stark law falls outside the scope of the agency's advisory opinion authority. Pursuant to § 205 of the Health Insurance Portability and Accountability Act of 1996, DHHS was directed to issue written advisory opinions addressing (1) what constitutes prohibited remuneration under the Anti-Kickback Statute; (2) whether an arrangement satisfies one of the Statute's statutory exceptions or regulatory safe harbors; (3) what constitutes an inducement to limit services to Medicare beneficiaries under the CMP Statute; and (4) whether an activity constitutes grounds for the imposition of civil or criminal sanctions under §§ 1128, 1128A, or 1128B of the Social Security Act. Thus, the OIG is not authorized to address whether an arrangement runs afoul of the Stark law in its advisory opinions.

B. CMS Guidance

Technically speaking, application of the Stark law falls within the purview of the Centers for Medicare and Medicaid Services (CMS), the DHHS division with primary responsibility for the development of the Stark regulations. Although CMS has advisory opinion authority,⁶ it has been reluctant to utilize this authority, issuing only two substantive Stark advisory opinions in late 1998.⁷

CMS' guidance on gainsharing arrangements has been limited. In September 2003, CMS approved a demonstration project awarded to the New Jersey Hospital Association. Pursuant to the demonstration project, when a hospital's Medicare payment was greater than the actual cost of furnishing the care, a portion of the differential would go into a pool and be available for bonus payments to physicians. The primary purpose of the project was to allow hospitals to make incentive payments to physicians as a reward for furnishing high quality care in a cost effective manner.

In a suit filed in the U.S. District Court for the District of New Jersey, a group of hospitals sought to prevent the implementation of the demonstration project. The plaintiffs alleged, among other things, that the project violated the Anti-Kickback Statute, the CMP Statute, and the Stark law. With respect to the Stark law, the district court found that statute authorizing DHHS to pursue demonstration projects effectively waived compliance with the Stark law. The court, however, ultimately enjoined CMS from moving forward with the demonstration project, ruling that the project was "in fatal conflict" with the CMP Statute. *Robert Wood Johnson University Hospital v. Thompson*, No. 2:04-CV-00142 (D.N.J. April 15, 2004).

While the Secretary of DHHS was attempting to defend the New Jersey gainsharing demonstration project, CMS published the Stark II, Phase II Interim Final Rules. In the preamble to the Interim Final Rules, CMS furnished the industry with some indication of its views on how gainsharing arrangements would fare under the Stark law.⁸ Specifically, CMS addressed comments requesting that the employment exception to the Stark law be interpreted to permit hospitals to pay employed physicians incentives for meeting hospital or drug utilization targets. The commenters asserted that such payments should not be construed as based on the volume or value of referrals for the purposes of the Stark law. CMS had the following response:

There is no exception in the statute or in these regulations that would permit payments to physicians based on their utilization of DHS [designated health services], except as specifically permitted by the risk-sharing arrangements, prepaid plans, and personal service arrangements exceptions. None of those exceptions permit those payments other than in the context of services provided to enrollees of certain health plans. We believe that the Congress intended to limit these kinds of incentives consistent with the civil monetary penalty provision at 1877(e)(2)(D) of the Act to add additional requirements to the employment exception that is limited to requirements needed to protect against program or patient abuse. Since section 1128A(b)(1) of the [CMP Statute] represents a legislative determination of potential abuse, we cannot create an exception for those activities.⁹

III. Gainsharing Arrangements and the Stark Law

So how does one reconcile CMS' 2004 Stark law preamble language with the OIG's favorable Advisory Opinions? Is there a disconnect between the Industry Guidance section of the OIG (the division responsible for issuing advisory opinions) and those CMS representatives responsible for overseeing the development of the Stark regulations?

The OIG's admonitions are correct as a matter of law: the Stark law falls outside its advisory opinion jurisdiction. Accordingly, the OIG's decision not to address the application of the Stark law in the Advisory Opinions is consistent with its statutory mandate. By the same token, senior OIG representatives played a critical role in developing both the Phase I (2001) and Phase II (2004) Stark regulations and the accompanying preamble commentary. Thus, one cannot help but wonder whether the OIG would issue six consecutive advisory opinions approving gainsharing arrangements without giving consideration to whether such arrangements implicate or violate the Stark law?

We hope the answer to this vexing question is “no,” for if the OIG concurs with CMS’ view that no Stark law exception would allow hospitals to pay physicians based on their utilization of hospital services, other than in the context of services provided to enrollees of certain health plans, then the OIG may be doing the industry a disservice by issuing the Advisory Opinions. After all, query whether the OIG’s Industry Guidance Branch would be fulfilling its obligation to provide meaningful, practical advice on the Anti-Kickback and CMP Statutes by approving arrangements that cannot meet an exception to the Stark law.

A. Pattern of Inconsistency?

The OIG appears to have issued at least one favorable advisory opinion under the Anti-Kickback Statute with respect to an arrangement that may be incapable of meeting a Stark law exception. In Advisory Opinion 04-19 (issued December 30, 2004), the OIG considered an arrangement pursuant to which a hospital would provide malpractice insurance subsidies to a two-neurosurgeon practice group. As described in the advisory opinion, the hospital/requestor was faced with a situation in which, despite the hospital’s recruitment efforts, there were only two neurosurgeons practicing in the community and, on short notice, the surgeons’ insurance carrier notified them that it (a) would not renew their malpractice insurance, and (b) would provide free tail coverage if the surgeons retired. Consequently, the two surgeons notified the hospital that they would retire immediately unless the hospital subsidized their malpractice insurance expenses. The hospital agreed to pay for tail coverage for the physicians (from their old carrier) and subsidize a portion of the physicians’ “claims made” and tail coverage (from a new carrier) for a two-year period.

The OIG concluded that, notwithstanding its historical concern with malpractice insurance subsidies, it would not subject the parties to administrative sanctions. The agency’s reasons were four-fold. First, the arrangement was implemented as a “temporary and urgent measure” to prevent a gap in the availability of neurosurgical services in the community. Second, the arrangement was structured to prevent a windfall for the physicians; indeed, even with the hospital’s subsidies, each physician ultimately paid more for malpractice insurance under the arrangement than he or she did previously. Third, the risk of “undue benefit” to the physicians was reduced because they were required to (1) furnish certain services to the hospital under the arrangement (e.g., call coverage and serve on hospital committees), and (2) maintain a full-time practice in the community and continue providing care to Medicare and Medicaid beneficiaries. Finally, there was no requirement that the physicians refer patients to or generate business for the hospital, although they were required to maintain hospital privileges.

Advisory Opinion 04-19 was hailed as a pragmatic (and wise) solution to an urgent problem created by the growing mal-

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practice insurance crisis faced by many medical specialties around the country. Before long, 04-19 was widely touted in many regulatory and compliance circles as the proverbial “green light” for the development of sensible malpractice premium support programs. Few raised Stark law concerns. After all, common wisdom assured, there is no way that the OIG would bless an arrangement under the Anti-Kickback Statute when its implementation would subject the parties to the harsh penalties attendant to a Stark law violation. Analysis of the arrangement in 04-19 (which is not all that different from the analysis of the gainsharing arrangements in the Advisory Opinions), suggests that this assurance may have been misplaced, however.

B. The Stark Law Analysis

1. Elements

Most of the elements of a Stark law violation are present in the OIG-approved gainsharing arrangements. Specifically, the arrangements involve “physicians” (cardiologists or cardiovascular surgeons) who “refer” Medicare beneficiaries to

the hospitals at issue for the “furnishing” of designated health services (DHS) (e.g., inpatient and outpatient hospital services). For example, the Stark law’s referral and billing prohibitions would be potentially triggered each time one of the cardiologists ordered a catheterization procedure for a Medicare beneficiary, the procedure was performed in the hospital’s cath lab, the physician had a financial relationship with the hospital, and no exception was available.

Accordingly, the next question in the analysis is whether a “financial relationship” exists between a referring physician and a hospital as a result of their participation in a gainsharing arrangement. This analysis is based exclusively on the limited information available in the Advisory Opinions and certain reasonable assumptions drawn from the fact that the OIG issued a favorable response.

2. Financial Relationship

The Stark law defines a “financial relationship” as either an ownership or investment interest in an entity furnishing DHS or a compensation arrangement between the referring physician (or an immediate family member) and the DHS entity. As an initial observation, there is nothing about the gainsharing arrangements that gives rise to a physician’s ownership or investment interest in the hospital at issue. Thus, if a financial relationship exists as a result of the gainsharing arrangements, it will take the form of a compensation arrangement. There are two principal types of compensation arrangements: a “direct” compensation arrangement and an “indirect” compensation arrangement.

A physician has a “direct” compensation arrangement with a hospital when remuneration—i.e., anything of value—passes directly between the physician and the hospital without any intervening persons or entities.¹⁰ For example, when a physician enters into a personal services agreement with a hospital pursuant to which the physician receives payment for the provision of administrative services, a direct compensation arrangement exists between the physician and the hospital. If a physician is employed (and paid) by a practice group and the practice group, in turn, has a contract with (and is paid by) the hospital to furnish administrative services to the hospital, then the physician has a direct compensation arrangement with the practice group, but not with the hospital.

Neither the insurance subsidy payments at issue in 04-19 nor the gainsharing arrangements in the Advisory Opinions would appear to involve direct compensation arrangements. Put simply, under these arrangements, payment is made by a hospital to an intervening party—namely, the physician group. Thus, the analysis focuses on whether the arrangements give rise to one or more indirect compensation arrangements.

3. Indirect Compensation Arrangement Defined

In order for a physician to have an “indirect compensation arrangement” with a hospital, three conditions must be satisfied. *First*, there must be an “unbroken chain” (between the referring physician and the DHS entity) of any number of intervening persons or entities that have financial relationships between them.¹¹ These intervening relationships may take the form of ownership/investment interests or compensation arrangements.¹² Moreover, they may individually satisfy the requirements of another Stark law exception. In CMS’ own words, “a direct financial relationship can form a link in a chain of financial arrangements that creates an indirect compensation arrangement, even if the direct financial relationship qualifies for an exception.”¹³

The gainsharing arrangements create two unbroken chains of financial relationships, as follows: (a) hospital → 50% of cost savings → physician group → profit distributions → physician owners; and (b) hospital → 50% of cost savings → physician group → per capita distribution → physician employees and contractors. (Note that the arrangement described in 04-19 gave rise to two very similar chains, one involving the neurosurgeons as shareholders or owners of the group and the other involving the neurosurgeons as employees of the group.)

Second, the referring physician’s *aggregate* compensation must vary with, or otherwise reflect, the volume or value of referrals or other business generated by the referring physician for the DHS entity at issue—in this case, the hospital.¹⁴ In the context of a cardiologist or cardiovascular surgeon employed by the group involved in the gainsharing arrangements, we would look to the compensation arrangement between the group and the individual physician to determine whether his or her compensation varies with or otherwise reflects the volume or value of referrals or other business generated by that physician to the hospital. If this is not the case—i.e., if the aggregate compensation received by the employed physician from the group does not vary with or otherwise reflect the volume or value of referrals to (or other business generated for) the hospital—then the second prong of the definition is not met. As such, there would be no “indirect” compensation arrangement between the physician and the hospital, leaving the physician free to refer Medicare patients to the hospital for the furnishing of DHS without violating the Stark law (assuming, of course, that he or she did not have another, unexcepted financial relationship with the hospital).

On the other hand, if the referring physician has a direct *ownership* interest in the chain of financial relationships at issue—as will be the case when the cardiologist or cardiovascular surgeon is a shareholder in (or owner of) the group—then the second prong of the indirect compensation definition focuses on the first relationship in the chain of unbro-



ken financial relationships (i.e., the relationship closest to the physician) that is a “compensation arrangement.”¹⁵ In the case of gainsharing, the inquiry would focus on the compensation arrangement between the hospital and the physician group itself; and the question would be whether the aggregate compensation received by the group from the hospital under the gainsharing arrangement (e.g., 50% of cost savings) varies with, or otherwise reflects, the volume or value of referrals or other business generated by the physician-owner for the hospital.

CMS provided the following example in the preamble to its 2001 Phase I Stark II regulations: a physician owns a physical therapy (PT) company; PT company contracts with a skilled nursing facility (SNF) to provide PT services to SNF’s patients on a per service basis; and, physician refers patients to SNF for treatment, including PT services. According to CMS, “[s]ince the PT company is compensated on a per service basis that reflects referrals by the referring physician to the SNF, the second element is met.”¹⁶ Put differently, under the arrangement, the physician could improve his financial position (by ensuring per service payments from the SNF to the PT company) every time he referred a Medicare patient (who required therapy services) to the SNF. According to CMS, “we look to the compensation paid by the SNF to the owned entity (that is, the PT company) in order to see if the second element is satisfied.”¹⁷

The question of when an arrangement involves compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated is complex and, accordingly, the source of perennial confusion. The confusion appears to stem, at least in part, from the fact that the Phase I Stark II regulations set forth “[s]pecial rules on compensation,” which, in relevant part, describe when certain unit-based compensation arrangements (such as per procedure or per click payments) are deemed not to trigger the Stark law’s “volume or value” or “other business generated” standards.¹⁸ Pursuant to these special compensation rules, for example, a hospital may pay a physician a per procedure fee of \$100 each time the physician performs a particular medical procedure without having such payment trigger the “volume or value” standard, provided that \$100 represents fair market value for the service and does not vary during the course of the arrangement.¹⁹ CMS, however, appears to be of the view that “when considered in the aggregate,” time-based or unit-of-service compensation arrangements “always” trigger the “volume or value” standard, even if—indeed, regardless of whether—they meet the requirements of the special compensation rules set forth in 42 C.F.R. §§ 411.354(d) (2) and (3).²⁰

Specifically, CMS stated that “time-based or unit-of-service-based compensation will always vary with the volume or value of services when considered in the aggregate”²¹ The authors find this reference to “services” curious because

the regulation itself focuses on whether the referring physician’s “aggregate compensation varies with, or otherwise reflects, the volume or value of [his or her] referrals,” and not his or her “services.”²²

One possible interpretation of the regulation is that the phrase “otherwise reflects” has a different—and potentially broader—meaning than the phrase “varies with.” Although neither phrase is defined in the regulations or the preambles to the regulations, the authors predicate their conclusion on three factors.²³

First, if the two phrases were interchangeable, there would have been no reason for CMS to use both phrases in the same sentence.

Second, the plain meaning of the words “varies” and “reflects” supports this conclusion, with the latter term being the broader and more far-reaching of the two. The use of the word “otherwise” before the word “reflects” further supports the view that “reflects” covers more than “varies” for purposes of this second prong of the indirect compensation arrangement definition. As discussed below, the distinction between these two phrases may have fundamental, practical—and not just academic—ramifications.

Third, in order to meet the definition of an indirect compensation arrangement, the DHS entity must have actual knowledge (or must act in reckless disregard or deliberate ignorance) of the fact that the referring physician’s aggregate compensation satisfies the second prong of the definitional test. CMS takes the position that this third condition imposes a “duty of reasonable inquiry” on the furnishing entity.²⁴

4. Indirect Compensation Arrangement Definition Applied

So do the gainsharing arrangements at issue in the Advisory Opinions create an indirect compensation arrangement between and among the physicians in the group and the hospitals? Our analysis follows.

First, Unbroken Chain of Financial Relationships. As previously noted, the first prong of the test is met. In fact, the arrangements would appear to give rise to two separate unbroken chains of financial relationships, one involving physician shareholders or owners and the second involving physician employees.

Second, Aggregate Compensation. Application of the second prong—i.e., determining if the physician’s aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the hospital—requires additional information about how the group members are compensated. According to the Advisory Opinions, participating groups are paid 50% of the cost savings achieved as a result of their involvement in the gainsharing program. The groups, in turn, will distribute the savings to their physicians on a per

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capita basis. With this information, we can attempt to apply the second prong of the definitional test, but in order to do so, we must distinguish those physicians who are shareholders or owners of the group from those physicians who are employees of the group.

Physicians as Shareholders/Owners of the Group. In the case of the group's physician shareholders or owners, the second prong focuses on the closest relationship in the chain of financial relationships that is a compensation arrangement. In other words, the focus is on the direct compensation arrangement between the hospital and the group practice (i.e., the payment of 50% of the cost savings generated as a result of the group's participation in the gainsharing program), and the relevant inquiry is whether, in the aggregate, this compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the physician-shareholders/owners. The answer appears to be "yes."

At bottom, if the participating physicians do not refer patients to the hospital, then no cost savings would be generated and, as such, there would be no savings for the hospital to share with the group. In other words, the only way for physicians to generate cost savings is to refer patients to the hospital and provide them with care that is consistent with the cost-savings recommendations of the gainsharing program. Indeed, group physicians know that every time they refer a patient to the hospital and follow the gainsharing protocol (such as ordering a less expensive device), there will be a corresponding opportunity for the group to earn 50% of the resulting cost savings.

Physicians as Employees of the Group. We assume that the employed physicians are paid a salary and offered a potential bonus based on personally performed medical services. Additionally, each physician is eligible for a per capita portion of any savings achieved by the gainsharing program. As such, an individual physician's aggregate compensation from the group may not vary with the volume or value of referrals or other business generated by him or her for the hospital. It is less clear whether the per capita payment can be said not to "otherwise reflect" each physician's referrals to or business generated for the hospital. By definition, there would be no cost savings generated and, a fortiori, no per capita distributions unless the group's physicians referred Medicare and other patients to the hospital.

Third, Hospital Knowledge. The third prong requires that the hospital know (or have reason to know) that the referring physician's aggregate compensation satisfies prong two. In the Advisory Opinions, the hospitals had an active role in the structure of the gainsharing arrangement and, as such, complete awareness of its financial implications. Therefore, the last requirement of the definition of an indirect compensation arrangement is likely satisfied.



Assuming, and for purposes of this article we do, that the gainsharing arrangements in the Advisory Opinions give rise to an indirect compensation arrangement between the physicians in the cardiology or cardiovascular surgery groups and the hospital, then the arrangement will violate the Stark law in the absence of an exception. The only possibly applicable exception is the indirect compensation arrangements exception.

5. Exception for Indirect Compensation Arrangements

Like the definition, the exception for indirect compensation arrangements has three prongs. Each of these prongs is analyzed separately for (1) physician-shareholders/owners, and (2) physician-employees.

Physician Shareholders/Owners—Prong 1. The first prong of the exception provides that the referring physician's compensation must be (a) fair market value, and (b) determined in a manner that does *not* take into account the volume or value of referrals or other business generated by the physician for the DHS entity (i.e., the hospital). For physician-shareholders/owners, the focus of the analysis is on the compensation arrangement between the hospital and the group—i.e., the same “link” in the chain of financial relationships that was analyzed above in connection with the definition of indirect compensation arrangements.

The first component of the inquiry is whether the compensation paid by the hospital to the group is fair market value (FMV) for items and services actually provided. Establishing that a 50% of cost-savings payment represents FMV for services provided may present challenges.

Healthcare fraud and abuse analyses—whether conducted under the Anti-Kickback Statute or the Stark law—are typically grounded in the reality of the arrangements under consideration. The reality of gainsharing arrangements is that they have little to do with paying physicians for specific services furnished to the hospital (such as defined medical director or quality assurance services). Rather, their *raison de être* is to provide physicians with a meaningful financial incentive to alter their clinical conduct and adhere to the gainsharing protocol. Among other things, the protocol requires the physicians to engage in product standardization with respect to certain high-cost items (e.g., coronary stents). Thus, if a participating physician who historically utilized a device that cost the hospital \$4,500 agrees to use a device that costs only \$2,100, the \$1,400 in cost savings generated will result in a \$700 payment to the physician's group every time he or she orders the less costly device. Tying the group's \$700 payment to services actually needed and provided by the physician is likely, in our view, to be undermined by the reality that the payment constitutes remuneration to induce the physician to order and use the cheaper device.

There is no question that the gainsharing arrangements contemplate the expenditure of real time and effort on

behalf of the participating physicians. The relationship between such time and effort and the 50% payment, however, may be too attenuated to withstand FMV scrutiny, particularly in the context of the Stark law and CMS' suggested use of methodologies for calculating hourly rates that will be “deemed” to meet FMV for physician services.²⁵ Given the amount of savings that gainsharing programs promise to generate, the payment to the group could be disproportionately high when evaluated against CMS' deeming provisions. Moreover, the Advisory Opinions are silent with respect to any obligation of participating groups (or their physicians) to document their time and effort relating to the gainsharing programs. Again, reality harkens: this is not a payment for services, FMV or otherwise.

The second component of the inquiry is whether the hospital's payment of generated cost savings—without regard to the “aggregate”—“takes into account” (1) the volume or value of referrals, or (2) other business generated by the participating physician for the hospital. As noted above, when compensation does not have to be considered in the aggregate, the “special rules on compensation” govern; these rules provide that the volume/value and other business-generated standards are not implicated by unit-based payment methodologies, provided the unit payment does not vary during the course of the compensation arrangement.

Notably, however, neither standard contemplates percentage-based compensation methodologies. Thus, looking only at the plain language of this prong of the exception and the relevant definitions outlined above, it appears that the group's compensation (i.e., 50% of savings) would trigger both standards. Again, as set forth above, a participating physician will trigger a percentage-based savings payment every time he or she refers a patient to the hospital and follows the gainsharing protocol. Thus, the percentage of savings methodology does take into account the volume or value and other business generated by the physician for the hospital.

Importantly, in 2004, CMS indicated that, in order to permit physician contractors to be compensated in a manner that is more consistent with the compensation of physician employees, it was changing the “set in advance” section of the special rules on compensation to permit percentage-based compensation arrangements.²⁶ Unfortunately, CMS did not make parallel changes to the volume/value and other business-generated sections of the special rules on compensation. Only time will tell if this omission was deliberate or inadvertent. In the interim, however, the regulations provide that percentage-based payments do trigger the volume/value and other business generated standards.

Physician Owners—Prong 2. The second prong of the exception requires that the compensation arrangement between the hospital and the group be set out in writing, signed by the parties, and specify the services covered by the arrangement. These requirements likely are met by the gainsharing

arrangements approved in the Advisory Opinions, and presumably, most other gainsharing arrangements.

Physician Owners—Prong 3. The third prong requires that the gainsharing arrangement (in its entirety) not violate the Anti-Kickback Statute or any other federal or state authority governing billing or claims submission. Compliance with this prong may be satisfied if, among other things, the parties satisfy a statutory exception or regulatory safe harbor to the Anti-Kickback Statute, or obtain a favorable OIG advisory opinion. Thus, the Anti-Kickback component of this prong is satisfied with respect to the gainsharing arrangements approved in the Advisory Opinions. The same cannot be said with respect to future gainsharing arrangements or existing gainsharing arrangements not reviewed by the OIG. First, the OIG concluded in the Advisory Opinions that the arrangements probably did involve “prohibited remuneration.” Second, the arrangements do not qualify for any Anti-Kickback statutory exception or safe harbor. Under these circumstances, satisfaction of prong three will depend on the parties’ willingness to submit the arrangement for an OIG advisory opinion—a process that currently may entail a two-year waiting period.

Next, we turn to the physician employees.

Physician Employees—Prong 1. As outlined above, the first prong of the indirect compensation exception provides that the referring physician’s compensation must be (a) fair market value, and (b) determined in a manner that does *not* take into account the volume or value of the physician’s referrals to or business generated for the hospital.

Establishing the FMV of the compensation furnished by a practice group to its physician employees is a fairly common and straightforward undertaking. The per capita distribution of the 50% of savings resulting from the gainsharing arrangement may introduce some complications. Assume, for argument’s sake, that a cardiology group comprising of ten cardiologists (all of whom are both owners and employees of the group) participates in a gainsharing program that yields a per capita distribution at the end of the gainsharing year of \$50,000 per physician. Assume further that while nine of the cardiologists adhered to the protocol in a good faith, disciplined manner, cardiologist ten essentially shied away from the program, referring most of his patients who required hospital services to another hospital in the community. Under these circumstances, cardiologist ten would receive the same \$50,000 payment as the other nine cardiologists, thereby undermining the proposition that the per capita distribution is a payment for items or services actually provided, let alone a payment that is at FMV.

The per capita distribution appears to have been used by the parties to dilute the ability of an individual physician to affect his or her financial return by making choices based on economic rather than clinical factors. Nonetheless, the

nexus between a physician’s referrals and the per capita payment may be sufficient to support the determination that the distribution varies with, or at least “reflects,” the physician’s referrals to and business generation for the hospital.

Physician Employees—Prong Two. The second prong requires that the employment relationship between the group and its member physicians be “bona fide,” for identifiable services, and commercially reasonable even if no referrals are made to the group. In general, so long as the physician employees are truly employed by the group to furnish medical services to the group’s patients, this component of the second prong should be fairly easy to satisfy.

Physician Employees—Prong 3. As discussed in connection with the analysis of the unbroken chain of financial relationships involving physician-shareholders/owners, the third prong of the indirect compensation arrangements exception focuses on the legality of the entire arrangement under the Anti-Kickback Statute and applicable laws governing billing and claims submission. As such, the same analysis applies, meaning that in the absence of an OIG advisory opinion, parties are unlikely to be in a position to satisfy this requirement.

IV. Conclusion

The purpose of this article is *not* to establish that the gainsharing arrangements recently approved by the OIG do not or cannot meet the requirements of a Stark law exception. As noted above, our analysis of these arrangements was, by necessity, limited to the information available in the Advisory Opinions themselves and certain narrow assumptions flowing reasonably from the OIG’s analysis and conclusions. As such, there may be information that, when considered, would support the conclusion that the arrangements do not implicate, or at least do not violate, the Stark law.

Rather, the purpose of this article is to identify potential limitations in the application of the available Stark law exceptions to these beneficial, innovative arrangements. We constantly remind ourselves and our clients that the Stark law is different than the Anti-Kickback Statute; in the end, the parties’ intentions (good or bad) are immaterial. If an arrangement between a hospital and a group of physicians possesses the requisite elements to implicate the Stark law (as may well be the case with the approved gainsharing arrangements), then an exception must be met, regardless of the virtues of the arrangement or the fact that the parties to the arrangement received a favorable OIG advisory opinion. Given some of the limitations in the Stark analysis discussed in this article and the need for “bright lines” when applying the Stark law, perhaps CMS should consider using its statutory authority to create an exception specifically addressing gainsharing arrangements, consistent with legislation recently proposed by Senators Charles Grassley

(R-IA) and Max Baucus (D-MT) in Senate Bill 1002. Otherwise, those hospitals and physicians participating in (or contemplating) gainsharing arrangements will lack the assurance of knowing that these arrangements do not violate the Stark law.

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End Notes

- ¹ Although not addressed in this article, tax-exempt providers contemplating gain-sharing arrangements also must grapple with the doctrines of private inurement and private benefit.
- ² DHHS-OIG Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999).
- ³ 42 U.S.C. § 1320a-7a(b)(1).
- ⁴ *Id.* at § 1320a-7a(b)(2).
- ⁵ Special Advisory Opinion (July 1999).
- ⁶ 42 U.S.C. § 1395nn(g)(6); 42 C.F.R. §§ 411.370-389.
- ⁷ Beginning in June 2004, CMS began issuing specialty hospital advisory opinions to advise requestors whether they met the “under development” requirement of the specialty hospital moratorium.
- ⁸ See 69 Fed. Reg. 16054 (Mar. 26, 2004).
- ⁹ *Id.* at 16088.
- ¹⁰ 42 C.F.R. § 411.354(a)(2). Both Congress and CMS have carved out several “things of value” from the otherwise sweeping definition of the term “remuneration.”
- ¹¹ *Id.* § 411.354(c)(2)(i).
- ¹² *Id.*
- ¹³ 69 Fed. Reg. at 16059.
- ¹⁴ *Id.* § 411.354(c)(2)(ii) (emphasis added).
- ¹⁵ *Id.*
- ¹⁶ *Id.*
- ¹⁷ 66 Fed. Reg. at 868.
- ¹⁸ 42 C.F.R. §§ 411.354(d)(2), (3).
- ¹⁹ *Id.*
- ²⁰ 69 Fed. Reg. at 16058-16059.
- ²¹ *Id.* (emphasis added).
- ²² 42 C.F.R. § 411.354(c)(2)(ii).
- ²³ It should be noted that although the regulation uses the phrase “varies with, or otherwise reflects,” the preamble to the Interim Final Rule confusingly uses the phrase “takes into account.” See, e.g., 69 Fed. Reg. at 16059.
- ²⁴ 66 Fed. Reg. at 865.
- ²⁵ 42 C.F.R. § 411.351.
- ²⁶ 69 Fed. Reg. at 16066.

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