Gainsharing: Regulatory Breakthrough, but Challenges Remain

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I. Introduction

Rarely does the federal government create a business opportunity involving health care providers paying their referral sources for performing services and ordering specified items at the providers’ facilities.

But this is precisely what the U.S. Department of Health & Human Services (“HHS”), Office of Inspector General (“OIG”) did in the first six advisory opinions issued this year. In Advisory Opinions Nos. 05-01 through 05-06, the OIG approved “gainsharing” arrangements that not only permit hospitals to share with physicians the savings “gained” as a result of cost-reduction measures implemented by the physicians, but expressly endorse standardization of medical supplies and devices.¹

(Not only did the OIG approve arrangements whereby a hospital may reward physicians for using a particular (pre-selected) medical device (in lieu of other, clinically equivalent devices), but the hospital may require the physicians to use the “standardized” clinically equivalent device, unless medically inappropriate for a particular patient.) Some characterize the Advisory Opinions as a regulatory breakthrough, while others are more suspect of, or entirely opposed to, the arrangements at issue. Either way, the Advisory Opinions have resuscitated a nationwide debate about the benefits, risks, and propriety of gainsharing.

For certain sectors of the health care industry, gainsharing arrangements are undeniably attractive. Ever in search of strategies to align the otherwise divergent interests of their medical staffs, hospitals are drawn to a business model that enables them to pay physicians to change their behavior and adhere to clinical protocols designed to enhance hospitals’ economic performance.

Gainsharing arrangements also offer hospitals the possibility of increased leverage to negotiate more substantial price reductions, which was previously unavailable with respect to high cost, clinical preference products. For example, a hospital that has the ability to “steer” all or a majority of the cardiac surgeons on its medical staff to use a single type of coronary stent (from a class of clinically equivalent stents) is likely to receive fairly attractive offers from competing stent manufacturers intent on securing the hospital’s business.

In sum, gainsharing has an obvious allure for hospitals struggling with ever-rising costs.

But hospitals are not the only beneficiaries of gainsharing arrangements. Hospital consultants, for one, have embraced the Advisory Opinions in the hope of developing a new and potentially lucrative line of business. Physicians, too, will likely see opportunities to in-

¹ OIG Advisory Opinion No. 05-01 (Jan. 28, 2005); OIG Advisory Opinion No. 05-02 (Feb. 10, 2005); OIG Advisory Opinion No. 05-03 (Feb. 10, 2005); OIG Advisory Opinion No. 05-04 (Feb. 10, 2005); OIG Advisory Opinion No. 05-05 (Feb. 18, 2005); OIG Advisory Opinion No. 05-06 (Feb. 18, 2005).
crease efficiencies, improve quality of patient care, and, of course, improve their financial lot.

The Office of Inspector General’s advisory opinions have resuscitated a nationwide debate about the benefits, risks, and propriety of gainsharing.

Not everyone in the health care industry has greeted the return of gainsharing with cheer, however. Many in government and patient advocacy circles are troubled by gainsharing. Their concern is straightforward: gainsharing arrangements create an inherent conflict of interest between a physician’s (1) duty to furnish patients with high quality medical care, and (2) desire to reduce or limit medical services in order to generate cost-savings and thus maximize his or her financial return under the gainsharing arrangement.

Representatives of the medical device manufacturing industry also are eyeing the recent reinvigoration of gainsharing with apprehension. As noted above, the incorporation of product standardization into gainsharing arrangements is likely to tighten the market for some manufacturers and heighten competition for all.

Moreover, within a matter of weeks after the six gainsharing Advisory Opinions were published, the U.S. Department of Justice (“DOJ”) issued subpoenas to at least five large manufacturers of orthopedic devices, seeking documents relating to their financial relationships with orthopedic surgeons. Although the DOJ investigation is at a very preliminary stage, one of its focal points appears to be whether the manufacturers at issue are using personal services agreements as a vehicle to pay orthopedic surgeons to order, purchase, or recommend their devices — a potential violation of the federal health care program anti-kickback statute (“Anti-Kickback Statute”), among other laws.

At bottom, the DOJ’s concern with manufacturer-physician relationships is a familiar one for the health care industry, and is essentially the same as the one at the core of the gainsharing debate: is it legal, and/or appropriate, to pay physicians to influence their clinical decision-making process?

The thematic overlap between gainsharing arrangements and the services agreements under DOJ scrutiny is further underscored by the fact that the gainsharing arrangements involved in the Advisory Opinions expressly (and boldly) required that medical specialists (namely, cardiologists and cardiovascular surgeons) engage in product standardization with respect to high cost, clinical preference devices.

It comes as no surprise then, that the OIG concluded that such arrangements violate the civil money penalty statute (“CMP Statute”) and potentially generate “prohibited remuneration” under the Anti-Kickback Statute. What does, or at least did, come as a surprise is that the OIG determined that the benefits of the gainsharing arrangements outweigh their potential for abuse and, as such, do not warrant the imposition of sanctions.

In the end, there is no question that the Advisory Opinions represent a significant regulatory (and public policy) development, reflecting the OIG’s recognition that: (1) hospital cost-savings are an ever-important policy objective; (2) achieving such savings requires the active cooperation of physicians on the hospitals’ medical staff; (3) such savings may be achieved through product standardization programs, particularly with respect to certain high-cost, clinical preference products; (4) physicians may need to be paid for their cooperation; and (5) all this may be achieved in a controlled fashion that would reduce the likelihood of program abuse and avoid a negative effect on the quality of patient care.

Yet, irrespective of whether gainsharing is viewed as good or bad, right or wrong, some important regulatory and practical questions remain unanswered. Possibly the most gaping hole in the analysis is whether the gainsharing arrangements give rise to an unexpected financial relationship under the federal physician self-referral law (commonly known as the “Stark Law”).

Given the severe financial consequences of violating the Stark Law, this issue must be addressed (and fully understood) by hospitals, physicians, and their consultants before they consider—let alone pursue—a gainsharing program in earnest. Moreover, the parameters of the gainsharing arrangements approved by the OIG are quite narrow and may pose challenges to parties attempting to structure a successful arrangement.

This article provides an overview of gainsharing, identifies some of the principal regulatory and practical challenges to the widespread adoption of gainsharing arrangements, analyzes the arrangements outlined in the recent Advisory Opinion under the Stark Law, and discusses possible next steps—all with the objective of sparking a constructive, public dialogue with respect to gainsharing.

II. Overview of Gainsharing

A. Definition of Gainsharing

While there is no single, uniform definition of gainsharing, in the health care industry the term usually refers to arrangements whereby hospitals and physicians agree to engage in certain cost-saving behaviors and share in the resulting cost-savings pursuant to some predetermined formula.

Essentially, these arrangements are one of the antidotes to a reimbursement environment that creates opposite financial incentives for physicians and hospitals. Hospitals are generally paid a fixed, pre-determined payment rate to provide all care for a particular patient’s diagnosis.

The care, however, is ordered by physicians, who are generally paid separately on a per service basis. Under Medicare, for example, hospitals typically are paid a single, prospectively-determined payment rate (Diagnostic Related Groups or “DRGs”) to treat their inpatients, irrespective of the actual cost of providing such care. Physicians, however, are paid separately under the Medicare Part B physician fee schedule. Physician compensation is not, therefore, impacted by the cost of the various medical supplies and devices they order for hospital patients.

2 See, DOJ Asks Implant Firms for Documents About Deals with Orthopedic Surgeons, 9 Health Care Fraud 292 (BNA April 13, 2005).
As such, hospitals are highly motivated to be cost-conscious, while physicians (who are the actual decision-makers with respect to care delivered by the hospital) have no parallel motivation, at least with respect to services furnished in the hospital setting.

Given this environment, the notion of “sharing” the savings “gained” from collective cost-reduction efforts has long piqued the interest of hospitals, physicians, and policy-makers alike. As explained below, however, early efforts at gainsharing arrangements were quashed by the OIG.

B. The OIG’s Historical Perspective

1. The 1999 Special Advisory Bulletin

In July 1999, the OIG issued a Special Advisory Bulletin addressing the application of the CMP Statute to gainsharing arrangements. Under the CMP Statute, a hospital is prohibited from knowingly making a payment (directly or indirectly) to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician’s direct care. 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. 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.”

The OIG did not direct that all existing gainsharing arrangements be dismantled. It cautioned, however, that it would “take into consideration in exercising its enforcement discretion whether a gainsharing arrangement was terminated expeditiously,” after the publication of the Special Advisory Bulletin. Not surprisingly, most risk-averse hospitals and physicians dissolved existing gainsharing arrangements, and plans to structure future arrangements were held in abeyance or abandoned entirely.

2. Advisory Opinion No. 01-01

Only two years later, the OIG issued a favorable advisory opinion on gainsharing. Advisory Opinion No. 01-01 involved a proposed arrangement whereby an acute care, not-for-profit hospital agreed to share — with a group of cardiovascular surgeons — a percentage of the hospital’s cost-savings arising from the group’s implementation of nineteen separate cost-reduction measures designed to “cure the inappropriate use or waste of medical supplies.”

The OIG grouped the cost reduction measures into three categories:

- **Opening Packaged Items.** Fourteen measures involved opening packaged items—such as surgical trays—only if such items were needed during a procedure.
- **Substitution of Products.** Four measures related to substituting (in whole or in part) less costly items for other items currently being used by the surgeons.
- **Use of Aprotinin.** The last measure related to Aprotinin, an anti-hemorrhaging drug often administered to preoperative patients. Aprotinin would be prescribed only for patients at a higher risk of hemorrhaging, as indicated by objective clinical standards.

Under the proposed arrangement, the hospital would pay the physician group 50 percent of the cost-savings achieved during a period of one-year. The group, in turn, would distribute its share of the realized savings on a per capita basis. No savings would be shared for an increase in volume over the base year, and significant changes in case-mix of patients could lead to termination of a physician’s participation in the arrangement.

The OIG identified four primary concerns with the proposed arrangement: (1) stinting on patient care; (2) “cherry picking” healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (3) payments in exchange for patient referrals; and (4) unfair competition (“race to the bottom”) among hospitals offering cost-sharing programs to foster physician loyalty and to attract more referrals. These concerns, in the OIG’s view, arguably implicated three legal authorities: the CMP Statute, the Anti-Kickback Statute, and the Stark Law.

a. CMP Statute

The OIG determined that all the cost-saving measures—except opening surgical trays “as needed”—ran afoul of the CMP Statute. Nevertheless, the OIG was persuaded that the arrangement contained sufficient safeguards to obviate the need for sanctions. Although the OIG enumerated numerous safeguards in Advisory Opinion No. 01-01, perhaps the two most critical safeguards involved (1) specificity and transparency, and (2) preservation of quality patient care.

- **(1) Specificity and Transparency**

  The OIG noted first that the “specific cost-saving actions and resulting savings are clearly and separately identified.” This type of transparency, the OIG stated, “will allow for public scrutiny and individual physician accountability for any adverse effects” of the proposed arrangement, including any difference in treatment based on non-clinical indicators.

  In addition, the hospital and physician group would provide written disclosures of the gainsharing arrangement to patients, providing them with an opportunity to review the cost-savings recommendations prior to admission to the hospital. In the OIG’s view, “effective and meaningful disclosures offer ‘some protection against possible abuses of patient trust’.”

- **(2) No Impact On Patient Care**

  The OIG also found that the parties to the proposed gainsharing arrangement “proffered credible medical support” that implementation of the recommendations, including the reduction in routine use of Aprotinin, will not adversely affect patient care.” Moreover, the OIG found it compelling that the recommendations

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3 OIG Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999) (hereinafter “Special Advisory Bulletin”).
4 42 U.S.C. § 1320a-7a(b)(1)-(2).
5 Id.
6 Special Advisory Bulletin (July 1999).
7 Id.
8 OIG Advisory Opinion No. 09-01 (Jan 2001).
9 Id.
10 Id.
11 Id.
12 Id.
13 Id.
14 Id.
would be periodically reviewed to confirm that patient care was not being compromised.\textsuperscript{15}

\textbf{b. Anti-Kickback Statute}

The OIG found that the proposed arrangement could result in “prohibited remuneration” under the Anti-Kickback Statute that, in effect, would induce or reward referrals by the cardiovascular surgeon group to the hospital.\textsuperscript{16} Although no statutory exception or regulatory safe harbor applied, the OIG did not impose sanctions on the parties for three reasons.

First, the OIG reasoned that the arrangement’s safeguards would “reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians.”\textsuperscript{17} Not only were the participating physicians already on the hospital’s medical staff, the OIG noted, but the limit of a one-year term would diminish “any incentive to switch facilities.”\textsuperscript{18}

Second, the OIG observed, the proposed arrangement eliminates the risk that it will be used “to reward cardiologists or other physicians who refer patients to the . . . [group] or its surgeons,” and mitigates any incentive for an “individual surgeon to generate disproportionate cost-savings.”\textsuperscript{19} Respectively, this is because (1) the group is composed entirely of cardiac surgeons, thereby precluding cardiologists or other physicians from sharing in the distributions, and (2) savings are distributed on a per capita basis.

Finally, because the arrangement “sets out with specificity the particular actions that will generate the cost-savings,” the OIG was willing to accept that a surgeon could be reasonably compensated for undertaking some increased liability exposure for changing his or her clinical practices.\textsuperscript{20} Importantly, the OIG did not opine on whether such compensation was at fair market value (“FMV”). It did, however, venture to say that such payments do not appear “unreasonable, given, among other things, the nature of the nineteen recommended actions, the specificity of the payment formula, and the cap on total remuneration to the . . . [group].”\textsuperscript{21}

\textbf{c. Stark Law}

Correctly noting that the Stark Law falls “outside of the scope of [its] advisory opinion authority,” the OIG, expressed “no opinion on the application” of the Stark Law in Advisory Opinion No. 01-01.\textsuperscript{22}

\textbf{C. The OIG’s Current Perspective: Advisory Opinions 05-01 Through 05-06}

In 2005, the OIG issued the six Advisory Opinions, concluding, as it did in Advisory Opinion No. 01-01, that the gainsharing arrangements at issue involve payments that violate the CMP Statute, and potentially violate the Anti-Kickback Statute (assuming the requisite intent were present), but that it would not impose sanctions on the parties. With a few, notable exceptions (discussed below), the facts of Advisory Opinions Nos. 05-01 through 05-06 are, in large part, similar to the facts of Advisory Opinion No. 01-01, and, as such, are summarized only briefly (and collectively) below.\textsuperscript{23}

\textbf{1. Facts}

All six arrangements involved an acute care hospital, a group or groups of physicians (either cardiologists or cardiac surgeons), and an outside “program administrator” that designed and monitored the one-year programs.\textsuperscript{24} Under the arrangements, each group could earn 50 percent of cost-savings achieved through the implementation of various recommendations. The groups, in turn, agreed to distribute their share of the cost-savings to their physicians on a per capita basis. The cost-savings recommendations fell into five categories: (1) open packaged items (e.g., surgical trays) only as needed; (2) perform blood cross-matching only as needed; (3) use surgical supplies (such as gelfoam, surgical, and vancomycin paste) only as needed; (4) substitute, in whole or part, less costly items for items currently being used (e.g., wrist splints, arm boards, aortic punches, and suture boots); and (5) standardize certain cardiac devices and supplies (e.g., stents, balloons, interventional guidewires and catheters, vascular closure, diagnostic devices, pacemakers, and defibrillators), unless medically inappropriate for a particular patient.\textsuperscript{25}

\textbf{2. Analysis of Product Standardization}

The OIG’s legal analysis of the six arrangements closely tracks its analysis in Advisory Opinion No. 01-01. Once again, the OIG determined that although the arrangements violate the CMP Statute, and potentially violate the Anti-Kickback Statute, the parties had implemented sufficient safeguards to protect against program abuse and a reduction in patient care. As such, the OIG decided not to impose sanctions. The Advisory Opinions are qualitatively different from Advisory Opinion No. 01-01, however, in that the OIG approved, for the first time, recommendations related to product standardization of high cost, clinical preference items.

In Advisory Opinion No. 05-05, for example, a cardiology group agreed to collaborate with the hospital to evaluate, select, and use specific products. Important safeguards, however, were incorporated to protect against inappropriate reductions in services. Of greatest importance to the OIG was that the parties certified that “individual cardiologists will make a patient-by-patient..."
determination of the most appropriate device” and “will still have available the same selection of devices” notwithstanding the gainsharing arrangement so as to ensure that the savings “result from inherent clinical and fiscal value and not from restricting the availability of devices.”

Thus, in enumerating the conditions relevant to its approval of a gainsharing arrangement, the OIG added another safeguard to the list set forth in Advisory Opinion No. 01-01. Specifically, the OIG noted that the product standardization portion of an arrangement must protect against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the arrangement as before.27

In addition, the arrangements imposed volume controls. In other words, the physicians do not share savings to the extent that any one of them exceeds the volume of a particular procedure he or she performed in the base year. This safeguard dilutes the incentive for physicians to increase their referrals to the hospital with which the physician has a gainsharing arrangement.

Finally, although the Advisory Opinions addressed product standardization with respect to a broad spectrum of cardiac devices, there appears to be nothing that would preclude such standardization in other medical specialties such as orthopedics. In other words, gainsharing would apparently be applicable to the entire range of medical devices.

III. Practical and Structural Limitations

Taken as a whole, the universe of gainsharing arrangements approved by the OIG to date remains narrow. In fact, although it could be argued that the OIG has, in the recent Advisory Opinions, taken a conceptual “leap” in permitting product standardization, it arguably has landed in a place that—from a practical and legal viewpoint—is still fairly cramped, and potentially inhospitable.

The principal limitations and constraints are as follows:
- **Limited Duration.** The OIG has placed a great deal of emphasis on the fact that it was approving arrangements of limited (i.e., one-year) duration. It is far from clear whether the OIG would approve arrangements with longer payout periods. It also is unclear whether the cost-savings realized during the one-year payout period could be sustained once the financial incentives driving hospital-physician alignment are removed. In other words, would physicians revert to their old behavior patterns once the payout period ended? If the answer is “yes” or even “in large part, yes,” it may make little economic (or, frankly, clinical) sense for parties to expend the resources to structure and implement a gainsharing arrangement only to have the benefits disappear upon its expiration. A number of reasonable strategies could be designed to prevent this type of “recidivism” (such as spreading the 50 percent payout of the first year savings over a period of two years or more). However, it is unclear whether this arrangement would be acceptable to the OIG or of sufficient interest to physicians.
- **Clinical Equivalence Analyses.** In approving the Advisory Opinion arrangements, the OIG also relied on “credible medical evidence” (submitted by the parties, and independently verified by the OIG’s own expert) that demonstrated that the cost-savings recommendations would not have an adverse effect on the quality of patient care because physicians would be rewarded only for shifting within categories of clinical equivalence. Unfortunately, there is a dearth of information in the public domain concerning what the OIG deems “credible.” We do know that the OIG did not accept the parties’ clinical equivalence suggestions in their entirety. As noted in the Advisory Opinions, some of the product standardization and substitution ideas were rejected. Which ideas were rejected and the reasons underlying their rejection remain unknown.
- **Limited Savings-Sharing.** The OIG has only approved programs that limit the amount of cost-savings shared with the physician groups to 50 percent.
- **Payout Shared Equally.** The savings must be distributed on a per capita basis to participating physicians.
- **Full Selection of Devices Maintained.** For any gainsharing arrangements involving standardization, the hospital must make available the full range of devices that were available to the physicians prior to gainsharing. This means that hospitals will likely need to continue to stock a variety of devices.
- **Volume Controls.** A physician cannot share savings to the extent that he or she exceeds the volume of a particular procedure in the base year.
- **Severity of Case-Mix.** In order to control potential “cherry-picking,” the case-mix of each participating physician must be monitored. If the characteristics of a physician’s admissions change significantly, that physician cannot participate in the gainsharing payouts.
- **Transparency.** The entire gainsharing arrangement must be transparent. This includes making written disclosures to patients (and others).
- **Specificity.** The OIG strongly favors arrangements based on “generalized” cost-savings that are not tied to specific, identifiable activities of the participating physicians. Hence, resources must be expended to determine and develop recommendations with the requisite degree of specificity.

IV. Legal Challenges

Even with the detailed roadmap of minimum safeguards outlined by the OIG, and seven examples of acceptable arrangements, formidable legal barriers remain to the widespread implementation of gainsharing.

A. The Need for an Advisory Opinion

One of the more significant hurdles for hospitals and physicians interested in implementing a gainsharing arrangement is the fact that an OIG advisory opinion protects only the parties that requested the opinion. Indeed, the OIG routinely admonishes the health care industry that no individual or entity—other than the requestor(s)—may rely on its advisory opinions. Typically, this caveat is glossed over as parties engage in a disciplined risk analysis that tracks the OIG’s analysis. In the context of gainsharing arrangements, however, the OIG has concluded (on at least eight separate occasions) that gainsharing arrangements violate the CMP

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20 OIG Advisory Opinion No. 05-05.
27 Id.
Statute, making the situation decidedly more complicated.

For example, is it reasonable for a hospital or a hospital system to implement an arrangement that it knows violates federal law on the assumption (or, more accurately, in the hope) that the OIG will exercise its discretion not to impose sanctions? Similarly, can in-house counsel or outside health care attorneys—who are bound by rules of professional conduct or responsibility to uphold the law—advise (and assist) their clients in pursing an illegal arrangement? These questions do not lend themselves to an easy or pragmatic solution. Rather, they suggest that parties should think long and hard before proceeding with a gainsharing arrangement that has not been reviewed and blessed by the OIG.

B. The Timing of an Advisory Opinion

Unfortunately, it is the authors’ understanding that, at present, it is taking the OIG approximately 18 to 24 months to shepherd an advisory opinion from beginning to end. This backlog could increase substantially, and arguably grind to a halt, as more parties elect to pursue gainsharing, but seek formal approval by the OIG. Given that the only way to avoid violating the CMP and Anti-Kickback Statutes is to obtain a favorable advisory opinion, relatively few gainsharing arrangements will be able to obtain this level of protection, at least in the near future.

C. The Stark Law Challenge

Finally, and as previously noted, the absence of formal government guidance concerning the application of the Stark Law to gainsharing is perhaps the most obvious and formidable obstacle to its widespread and systemic adoption. Due to the importance of this issue, a detailed Stark Law analysis of the gainsharing arrangements in the Advisory Opinions follows.

V. Stark Law Analysis

A. Overview of the Stark Law

The Stark Law prohibits a physician who (either directly or through an “immediate family member”) has a “financial relationship” with an “entity” from referring patients to that entity for the “furnishing” of “designated health services” (“DHS”) covered by Medicare, unless an exception applies.28 The Stark Law also prohibits the entity that has provided DHS to an improperly-referred Medicare patient from submitting a claim for reimbursement, or otherwise billing any person or entity, for such DHS.29

An entity that submits a claim in violation of the Stark Law must refund any amounts collected; it also may have to pay a civil penalty of up to $15,000 for each self-referred service,30 and be excluded from participation in federal health care programs.31

B. CMS’ Guidance on Gainsharing

Technically speaking, interpretation and application of the Stark Law falls within the purview of the Centers for Medicare & Medicaid Services (“CMS”). Although CMS has advisory opinion authority, it has been reluctant to utilize this authority, issuing only two substantive Stark Law advisory opinions in late 1998, neither of which had anything to do with gainsharing.32 CMS’ guidance regarding the application of the Stark Law to gainsharing has been limited.

In the preamble to the 2004 Stark II, Phase II Interim Final Rules, CMS did provide some indication of its views on how gainsharing arrangements would fare under the Stark Law.33 In addressing comments requesting that the Stark Law’s employment exception be interpreted to permit hospitals to pay employed physicians incentives for meeting hospital or drug utilization targets, CMS stated:

“There is no exception in the statute or in these regulations that would permit payments to physicians based on their utilization of DHS, 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.”34

The agency continued: “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.” 35

So how does the industry 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?

As set forth above, 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, raising the question whether the OIG would really issue six consecutive advisory opinions approving arrangements that implicate or violate the Stark Law? Logic and fairness suggest that the answer must be “no.” Unfortunately, the legal analysis suggests that the answer may be “yes.”

C. Principal Elements of the Stark Law

To determine whether an arrangement implicates the Stark Law, the following five questions must be answered:

1. Will a “physician” be making “referrals”?
2. If so, will the referrals be “to” an “entity”?
3. If so, will this entity be “furnishing” DHS?

29 Id. § 1395nn(a)(1)(B).
30 Id. § 1395nn(g)(2)-(3). This penalty may be imposed upon “[a]ny person who presents or causes to be presented a bill or claim” for improperly-referred DHS if the person “knows or should know” that the claim is for improperly-referred DHS. Id. § 1395nn(g)(3).
31 Id.

34 Id. at 16,088.
4. If so, will the DHS be covered by Medicare?
5. If so, does the physician have a “financial relationship” with the entity?

It would appear that all seven of the OIG-approved gainsharing arrangements unequivocally trigger an affirmative response with respect to the first four questions set forth above. Specifically, the arrangements involve “physicians” (i.e., cardiologists or cardiovascular surgeons); the physicians “refer” patients (including at least some Medicare beneficiaries) “to” an “entity” (i.e., the sponsoring hospital) whenever they order or request the hospital to “furnish” inpatient or outpatient hospital services to their patients; and, both inpatient and outpatient hospital services constitute DHS.

Accordingly, the next and final question in the “implication” analysis is whether a “financial relationship” exists between the referring physician and the sponsoring hospital by virtue of their participation in a gainsharing arrangement. If the answer is “yes,” then, regardless of the parties’ motivations or state of mind, the Stark Law will be implicated.

D. “Financial Relationship”

The Stark Law defines a “financial relationship” as a physician’s ownership or investment interest in, or a compensation arrangement with, the entity furnishing DHS. There is nothing about the gainsharing arrangements at issue in the Advisory Opinions that gives rise to an ownership or investment interest in the hospitals at issue. Thus, if a financial relationship exists as a result of a gainsharing arrangement, it will take the form of a compensation arrangement. There are two types of compensation arrangements: “direct” compensation arrangements and “indirect” compensation arrangements.

1. “Direct” Compensation Arrangements

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. 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.

None of the gainsharing arrangements reviewed by the OIG to date involved a direct compensation arrangement. Put simply, under all seven approved arrangements, the cost-savings were not shared directly with the physicians. Rather, the 50 percent of savings were transferred from the hospital to an intervening party—namely, the physician practice group—which, in turn, made per capita distributions to individual physicians. Thus, the question becomes whether the gainsharing arrangements give rise to one or more indirect compensation arrangements.

2. “Indirect” Compensation Arrangements

An “indirect” compensation arrangement exists if three conditions are met. 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. These intervening relationships may take the form of ownership/investment interests or compensation arrangements. Moreover, they may individually satisfy the requirements of another Stark Law exception. In CMS’ 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.”

The gainsharing arrangements create two unbroken chains of financial relationships:

(1) hospital 50 percent of cost-savings practice group profit distributions physician owners; and

(2) hospital 50 percent of cost-savings practice group salary plus per capita distribution physician employees and contractors.

Second, if the referring physician has a direct ownership interest in the chain of financial relationships at issue (as is the case with the first unbroken chain above), then the second prong of the indirect compensation definition focuses on the relationship in the chain that is closest to the physician and is a “compensation arrangement.”

In the gainsharing context, the inquiry focuses on the compensation arrangement between the hospital and the practice group itself (i.e., the payment of 50 percent of cost-savings); and the question would be whether, in the aggregate, this compensation varies with, or otherwise reflects, the volume or value of the physician-owners referrals to, or other business generated for, the hospital. On the other hand, if the referring physician has a direct compensation arrangement in the chain of financial relationships at issue (as is the case in the second unbroken chain above), then the second prong focuses on that compensation relationship.

The question of when an arrangement involves compensation that varies with, or otherwise reflects, the “volume or value” or “other business generated” standards is the source of perennial confusion. The confusion appears to stem, at least in part, from the fact that the 2001 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 these two standards.

Pursuant to these special 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 FMV for the service and does not vary during the course of the arrangement. CMS, however, appears to be of the view that “when considered in the aggregate, time-based or unit-of-service-based compensation arrangements ‘always’ trigger the ‘volume or value’ standard, even if—indeed, regardless of whether—they

30 The Stark Law (and its implementing regulations) define the term “referral” broadly to include orders or requests for items or services covered by Medicare Parts A or B. 42 U.S.C. §§ 1395nn(b)(5)(A), (B); 42 C.F.R. § 411.351.
31 Unlike the Anti-Kickback Statute, the Stark Law does not have a scienter, or “state of mind,” requirement.
33 42 C.F.R. § 411.354(c)(2)(i).
34 Id.
36 Id.
37 42 C.F.R. §§ 411.354(d)(2), (3).
38 Id.
meet the requirements of the “special compensation rules.”

According to CMS, “time-based or unit-of-service-based compensation will always vary with the volume or value of services when considered in the aggregate.” The reference to “services” is 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.”

In addition, it is worth noting that the phrase “otherwise reflects” may have a different—and potentially broader—meaning than the phrase “varies with.” Although neither phrase is defined in the Stark Law regulations, this interpretation is supported by three factors:

- If the two phrases were interchangeable, there would have been no reason for CMS to use both phrases in the same sentence.
- 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—or at least something different from—“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 ramifications for the viability of gainsharing under the Stark Law.

Third, in order to satisfy 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.

E. Application of the Indirect Compensation Definition To Gainsharing

1. Prong 1

As set forth above, the gainsharing arrangements at issue in the Advisory Opinions appear to give rise to two separate unbroken chains of financial relationships (one involving physician owners and the second involving physician employees), thereby satisfying the first prong of the definition.

2. Prong 2

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 separate treatment for those physicians who are owners of the group, and those physicians who are employees of the group.

a. Physician Owners

In the case of the group’s physician-owners, the relevant inquiry is whether, in the aggregate, the direct compensation arrangement between the hospital and the group practice (i.e., the payment of 50 percent of cost-savings), varies with, or otherwise reflects, the volume or value of referrals or other business generated by the physician-owners for the hospital. 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 gainsharing protocol. Indeed, every time a physician-owner refers a patient to the hospital and follows the gainsharing protocol (such as ordering a more cost-effective device), there will be a corresponding payment to his or her group.

b. Physician Employees

Each employed physician is eligible to receive a per capita portion of any savings achieved under the gainsharing program. Thus, a physician who makes twenty referrals that involve the gainsharing protocol will receive the same amount of money as a physician who makes only two referrals. As such, an individual physician’s aggregate compensation from the group may not vary with the volume or value of his or her referrals to, or other business generated for, the hospital. It is less clear whether the same can be said with respect to the “otherwise reflect” standard. 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 and complied with the gainsharing protocol. Therefore, it could be argued that the per capita distribution “reflects” the referrals and business generation of the participating physicians.

3. Prong 3

The third prong of the definition of indirect compensation arrangements 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 structuring the gainsharing arrangement and, as such, would be hard pressed to deny the requisite knowledge.

Thus, assuming, for purposes of this Article, that the gainsharing arrangements in the Advisory Opinions give rise to one (and possibly two) indirect compensation arrangements between the physicians in the groups and the relevant hospital, then the arrangement will violate the Stark Law in the absence of an exception. The only potentially applicable exception is the indirect compensation arrangements exception.

F. Exception for Indirect Compensation Arrangements

The exception for indirect compensation arrangements contains three prongs. First, the compensation arrangement in the unbroken chain of financial relationships closest to the referring physician must be (1) “fair market value” for services and items actually provided, and (2) determined in any manner that does not “take into account” the volume or value of referrals, or other business generated by the referring physician for...
the DHS entity. In contrast to the definition of indirect compensation arrangements, this prong is not measured against the physician’s aggregate compensation.

Second, with the exception of employment arrangements, the relevant compensation arrangement must be set out in writing, be signed by the parties, and specify the services covered by the arrangement.\(^{51}\) With respect to employment arrangements, the relationship between the employer and the employee must be a bona fide employment relationship, cover identifiable services, and be commercially reasonable even in the absence of referrals to the employer.\(^{52}\)

Third, the arrangement must not violate the Anti-Kickback Statute or any other law governing Medicare billing or claims submission.\(^{53}\)

G. Application of the Exception for Indirect Compensation Arrangements

As set forth above, the gainsharing arrangements at issue in the Advisory Opinions arguably create two separate indirect compensation arrangements among the participating physicians and the sponsoring hospital: one involving the practice group’s physician-owners; the other involving its physician employees. The application of the exception for indirect compensation arrangements is examined separately.

1. Physician Owners

a. Prong 1

The first prong of the exception provides that the referring physician’s compensation must be (1) fair market value, and (2) 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-owners, the focus of the analysis is on the compensation arrangement between the hospital and the group—i.e., the same “link” in the unbroken chain of financial relationships that was analyzed above in connection with the definition of indirect compensation arrangements.

(1) Fair Market Value

As noted, 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 percent of cost-savings payment represents FMV for services actually provided presents certain challenges.

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). The essence of gainsharing 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. Thus, if a participating physician who historically utilized a cardiac defibrillator that cost the hospital $5,000 agrees to use one that costs only $2,400, the $1,600 in cost-savings generated will result in an $800 payment to the physician’s group every time he or she orders the less costly device. Tying the group’s $800 payment to services actually provided is likely to be undermined by the reality that the payment constitutes remuneration to induce the physician to order and use the cheaper defibrillator.

Without doubt, the gainsharing arrangements contemplate the expenditure of real time and effort by the participating groups’ physicians. The relationship between such time and effort and the 50 percent payment, however, may be too generalized and attenuated to withstand FMV scrutiny, particularly when considered in the context of the conservative methodologies promulgated by CMS just last year (2004) for calculating hourly rates that will be “deemed” to meet FMV for physician services.\(^{54}\) Given the amount of savings that gainsharing programs have the potential to generate, the payment to the group has the potential to be disproportionately high when evaluated against CMS’ deeming provisions.

Moreover, it is telling that the Advisory Opinions are silent with respect to the potential applicability of the personal services and management contracts safe harbor to the Anti-Kickback Statute, and any obligation of participating groups (or their physicians) to document their time and effort—the linchpin of most personal services agreements between a hospital and referral sources. Again, reality harkens: this is not a payment for services, FMV or otherwise.

(2) Taking into Account

The second component of the inquiry is whether the hospital’s payment to the group—when considered 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 or 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, the rules do not extend the carve-out for unit-based compensation to percentage-based compensation methodologies. Thus, looking 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 percent of savings) would trigger both standards. Again, a participating physician triggers a percentage based savings payment every time he or she refers a patient to the hospital and follows the gainsharing protocol. Thus, the fifty percent (50%) of savings payment methodology would appear to take into account the volume or value and other business generated by the physician for the hospital.

Importantly, in 2004, CMS decided to change the “set in advance” section of the “special rules on compensation” to permit percentage-based compensation arrangements.\(^{55}\) In so doing, however, CMS did not make parallel changes to the volume or value and other business-generated sections of the special rules. Only time will tell if this omission was deliberate or inadvert-

\(^{50}\) Id. § 411.357(p)(1).

\(^{51}\) Id. § 411.357(p)(2).

\(^{52}\) Id.

\(^{53}\) Id. § 411.357(p)(3).

\(^{54}\) 42 C.F.R. § 411.351.

ent. In the interim, however, the regulations provide that percentage-based payments do trigger the volume or value and other business generated standards.

b. 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.

c. 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 Statute component of this prong is satisfied with respect to the gainsharing arrangements approved in the Advisory Opinions. The same cannot be said, however, with respect to future gainsharing arrangements or existing gainsharing arrangements not reviewed and approved by the OIG.

2. Physician Employees

a. Prong 1
Under the first prong of the indirect compensation arrangements exception, the compensation arrangement closest to the referring physician’s compensation must be (1) fair market value, and (2) 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 fifty percent (50%) of cost-savings may introduce some complications, however. Assume, for example, that a cardiology group comprised of eight cardiac surgeons (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 $80,000 per physician.

Assume further that while surgeons one through seven adhered to the gainsharing protocol, surgeon eight essentially shied away from the program, referring most of her patients to another hospital in the community. Under these circumstances, surgeon eight would receive the same $80,000 payment as the other seven, thereby arguably 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 returns under the arrangements. Nonetheless, the nexus between a physician’s referrals and the per capita payment may be sufficiently close to support a conclusion that the distribution takes into account the physician’s referrals to, and business generation for, the hospital.

b. Prong 2
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 will be met.

c. Prong 3
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 set forth above with respect to physician-owners applies, meaning that in the absence of an OIG advisory opinion, parties are unlikely to be in a position to satisfy this requirement.

VI. Conclusion

With the issuance of Advisory Opinions Nos. 05-01 through 05-06, the OIG has provided a great deal of guidance regarding the scope and structure of permissible gainsharing arrangements. The OIG should be commended for reexamining its position on gainsharing, broadening the manner in which hospitals and physicians may collaborate to achieve much needed hospital cost-savings (which ultimately may reduce Medicare expenditures as well), and reviving an important national dialogue about the alignment of hospital and physician incentives.

Such arrangements must be carefully considered and crafted, however, as under the current regulatory environment, they are likely to be subjected to numerous structural limitations and regulatory hurdles that may prove difficult (or at least cumbersome) to overcome.

The OIG should provide additional guidance that outlines permissible structures for longer payout periods, and specifies the criteria for clinical equivalency analyses. Further, the OIG should reconsider its position that gainsharing arrangements are presumed to violate the CMP Statute, as it is certainly not clear that influencing physician choice among clinically equivalent products necessarily violates this CMP Statute.

The OIG’s current position on this issue weighs heavily in favor of conditioning any gainsharing arrangements on the receipt of a favorable OIG advisory opinion. That, however, is not a very practical solution given the costs and delays associated with the advisory opinion process.

Finally, CMS should consider issuing its own guidance on the Stark Law issues, since gainsharing arrangements appear to give rise to financial relationships that trigger the Stark Law’s referral and billing prohibitions, but do not fit neatly into any of the Law’s existing exceptions.

The Medicare Payment Advisory Commission (“MedPAC”), has recognized that legislative intervention may be necessary.56

In a recent report to Congress, MedPAC observed: “Gainsharing has the potential to encourage physicians and hospitals to cooperate in developing more ef-

icient ways to deliver care, thus countering the sometimes conflicting payment incentives caused by the separate payment systems for physicians and hospitals under fee-for-service Medicare. The Commission believes that gainsharing arrangements have the potential to improve patient care and reduce hospital costs as long as safeguards are in place to minimize the undesirable incentives.  

As such, MedPAC argued, "Congress should provide the Secretary with the authority to allow and regulate these arrangements. The Secretary should develop rules that allow gainsharing arrangements as long as safeguards exist to ensure that cost-saving measures do not reduce quality or inappropriately influence physician referrals." Less than two months after MedPAC released its report, Sens. Charles E. Grassley (R-Iowa) and Max Baucus (D-Mont.) proposed S. 1002, which among other things, would require the secretary of health and human services to promulgate a formal rule specifying the requirements for acceptable gainsharing arrangements and providing immunity for compliant gainsharing arrangements under the CMP Statute, the Anti-Kickback Statute and the Stark Law.

Although the passage of Senate Bill 1002 does not appear imminent, such legislation may be the only practical solution to permit widespread pursuit and implementation of these important arrangements.

In the end, gainsharing presents a great opportunity for hospitals to work with physicians to reduce costs, which could lead to long term cost-savings for the Medicare program. However, for gainsharing to be widely adopted, the federal government must act either through legislation or the issuance of additional regulatory guidance to resolve the open legal issues.

57 Id. at 45.
58 Id. at 46.