

## **Valuation of Physician Consultant Arrangements: *Ensuring Compliance within the Medical Device Industry***

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### **Overview**

Regulatory restrictions within the healthcare industry often prohibit marketing practices that are common in other less regulated industries. For example, the federal anti-kickback statute places significant constraint on the marketing and sales practices of healthcare-related companies. This statute provides that *anyone who knowingly and willfully pays or receives anything of value to influence the referral of business, which is reimbursable in whole or in part by a federal healthcare program, can be charged with criminal penalties, civil monetary sanctions, and even exclusion from federal healthcare programs.*<sup>1</sup> As a result, fraud and abuse enforcement activities tend to focus on areas the government believes offer the potential for abusive arrangements, including arrangements between physicians and those entities that derive revenue from federal healthcare programs.

Clearly, relationships between medical device companies and physicians are encountering increased scrutiny from regulators. Questions are being raised with regard to the magnitude of payments to physician advisors and consultants, as well as possible conflicts of interest that may be inherent in these arrangements. The problem is that relationships between physicians and medical device companies are not black and white, and the relationships are perfectly permissible if structured appropriately.

Experienced physicians offer a level of expertise that often cannot be duplicated by any other group of professionals. As a result, their input into product design and development, as well as their insight into market requirements is invaluable. In fact, arrangements between medical device companies and physicians encompass a whole host of necessary services including product design, development, research/clinical trials, physician training and marketing. The government's concern with these types of arrangements revolves around the idea that they could be used as a vehicle to induce purchasing or prescribing of the company's products. Therefore, the government is focusing its attention on various types of consulting fee arrangements to determine if they are tied to prescribing practices or to usage patterns involving the company's products. In particular, the government is focusing its scrutiny on consulting arrangements, especially when the fees for these services appear to be in excess of fair market value (FMV) for actual services rendered. Similarly, medical device companies are being targeted for investigation when there is doubt as to the legitimate need for the particular consulting services, or when there is a lack of documentation of services rendered.

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<sup>1</sup> Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b))(2003)

## Recent Enforcement Actions

There have been several well-publicized enforcement actions for which the alleged illegal conduct included improper or sham consulting arrangements. For example, in July, 2006, Medtronic reached a settlement agreement with the U.S. Department of Justice in which it agreed to pay \$40 million to the United States and participating states to settle allegations stemming from two *qui tam* lawsuits.<sup>2</sup> These lawsuits, which were brought under the False Claims Act (FCA), allege that Medtronic made illegal payments to physicians to promote its spinal products in violation of the federal healthcare program anti kickback statute. The illegal payments included consulting and royalty agreements for which little or no work was performed as well as trips to lavish venues. In addition to the \$40 million payment, Medtronic was required to enter into a 5-year Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG).

In another well-publicized case, four major medical device manufacturers entered into civil settlement agreements with the government, which totaled \$311 million, to resolve allegations under the FCA. The government alleged that the companies provided financial incentives to physicians including consulting agreements and lavish trips to persuade physicians to use their joint replacement products. The government alleged that by offering illegal inducements, the identified companies violated the FCA by causing hospitals to seek and obtain reimbursement from Medicare. To avoid criminal prosecution, each of the identified companies entered into an 18-month deferred prosecution agreement, under which they agreed to multiple remedies including the posting, on their web sites, the names of consultants along with the aggregate payments to these consultants. In addition, each of the identified companies entered into a 5-year CIA.

Another well-publicized case involves a physician who accepted kickbacks from a medical device company in return for using the company's products. Even though criminal prosecutors have rarely directly targeted physicians, a physician who accepts a kickback in return for using a product can be as culpable as the company that provided the kickback. Dr. Patrick Chan, a neurologist in Arkansas, paid a \$1.5 million civil settlement in January, 2008, and pled guilty to soliciting and accepting kickbacks from Blackstone Medical. The kickbacks included gifts and payments for sham consulting agreements and fake research studies.

## Mitigating Risk

Since it is routine for medical device companies to engage physicians for the performance of multiple services, it is imperative to note that even if only one aspect of the remuneration for these services is to induce referrals, the anti-kickback statute is considered to be violated for the entire arrangement.<sup>3</sup> Therefore, key questions focus on determining *the best way to mitigate the*

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<sup>2</sup> *Qui tam* lawsuits are initiated by a third party on behalf of the government. These actions are generally brought by whistleblowers under the Federal False Claims Act (FCA).

<sup>3</sup> The OIG has the authority to pursue violations of the anti-kickback statute under a provision of the Civil Monetary Penalties Law (CMP). In kickback cases, CMP remedies include monetary penalties of up to \$50,000 for each act, including any offer, payment, solicitation or receipt of remuneration. In addition,

*apparent risk in relationships between medical device companies and physicians.* The anti-kickback statute<sup>4</sup> is extremely broad, and could literally apply to virtually all arrangements between physicians and medical device companies. Therefore, given the broad scope of the statute, the “personal services” safe harbor may provide an appropriate framework for structuring the arrangement.<sup>5</sup> The personal services safe harbor provides protection for arrangements with physicians as long as seven standards are met:

1. The agreement is set out in writing and signed by the parties;
2. The agreement identifies all the services to be provided by the physician as well as the term of the agreement;
3. If the agreement is intended to provide physician services on a sporadic or part-time basis, the agreement specifies the exact schedule of any intervals, their precise length and the exact charge for such intervals;
4. The term of the agreement is for not less than one year;
5. *The aggregate compensation paid to the physician over the term of the agreement is set in advance, is consistent with fair market value, and represents an arms-length transaction that is not determined in a manner that takes into consideration the volume or value of any referrals;*
6. The services performed under the agreement do not involve any activity that violates state or federal law; and
7. *The aggregate services contracted for under the agreement do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.*

Of particular focus of this paper are the requirements related to FMV and commercial reasonableness emphasized in italics above. Arguably, one of the most significant aspects of achieving the requirements of the personal services safe harbor involves establishing the FMV compensation associated with these arrangements. Fortunately, regulators agree that by basing compensation for legitimate services on a supportable FMV rate (assuming that the other requirements listed above generally have been met), the risk of payments being characterized as “in exchange for referrals” will largely be eliminated. However, defining FMV and developing methodologies to accurately determine FMV have proven to be a bit more elusive, as the government has historically provided little guidance on how FMV compensation should be calculated.

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under CMP, violators can be assessed up to three times the amount of remuneration, and face exclusion in federal healthcare programs.

<sup>4</sup> 42 U.S.C. § 1320a-7a(a)(7).

<sup>5</sup> Failure to comply with a safe harbor provision does not mean that an arrangement is illegal. Compliance with safe harbors is voluntary, and arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the anti-kickback statute.

## Defining and Establishing Fair Market Value

The term “fair market value” is generally defined as the value in arm’s-length transactions, consistent with the general market value. In the context of consulting or advisory arrangements between medical device companies and physicians, “general market value” means the compensation that would be determined as the result of *bona fide* bargaining between well informed parties to the agreement who are not otherwise in a position to generate business for the other party.<sup>6</sup>

Determining the FMV of compensation paid by a medical device company to a physician for advisory and/or consulting services is critical, but as indicated above, is not easily established. In particular, the volume or value of referrals cannot be considered in the determination (whether directly or indirectly), and market data cannot be considered to the extent that the data represents transactions between parties who are “in a position” to refer patients to one another. Therefore, compensation arrangements based on similar relationships should not be used as the sole determinant of FMV, as these arrangements may represent *tainted* values. This ultimately limits the techniques and data that healthcare valuers can use, and it makes FMV very difficult for medical device companies and physicians to determine or even understand. Moreover, the consequences associated with failure to accurately determine the FMV of physician advisor and consultant compensation can be catastrophic to all of the involved parties.

Although federal regulators have provided limited guidance with respect to establishing FMV, the previously described series of government settlements with medical device manufacturers concerning payments to physician consultants provides some insight into the scope of the problem. While the settlements are not applicable to other companies and their physician consultant arrangements, they provide some helpful direction with respect to identifying potentially risky transactions. The settlement agreements reiterated that compensation for such arrangements must be within FMV, and further, certain settlements require the manufacturers to seek *independent third party opinions* to establish FMV for any physician consultant compensation in excess of \$500 per hour.<sup>7</sup> In an interesting and perhaps confusing contrast, Hospital Corporation of America’s CIA from December 2000 required that HCA obtain an independent third party opinion for any physician consultant compensation in excess of \$150 per hour.

In fact, there is little valuation theory for an appraiser to rely upon in assessing these rather unique arrangements. The determination of the FMV of advisory and/or consulting relationships between

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<sup>6</sup> 42 CFR §411.351 (as set forth by the Centers for Medicare and Medicaid Services with respect to physicians’ referrals to health care entities with which they have financial relationships). Furthermore, this definition is consistent with similar fair market value guidance related to the Anti-Kickback Statute (42 U.S.C. §1320a-7b) and with the definition relied upon by the Internal Revenue Services. See, for example, Treas. Reg. 53.4958 et seq.

<sup>7</sup> See article entitled *Artificial-Joint Makers Settle Kickback Case*, New York Times, September 28, 2007, and the agreements between the U.S. Department of Justice and Biomet, DePuy Orthopedics, Zimmer Holdings, Stryker Orthopedics, and Smith and Nephew.

physicians and medical device companies entails a significant amount of judgment. Unlike clinical compensation data for physicians, very little survey information exists related directly to these types of compensation arrangements, which, in many instances may significantly exceed the proverbial 90<sup>th</sup> percentile values provided by physician compensation surveys. Further, advisory and consulting arrangements can be quite diverse, making comparisons among arrangements difficult. Finally, as mentioned above, a potential pitfall in looking to existing advisory and consulting arrangements as a basis for establishing FMV is that these relationships may be “tainted,” as they may contain an overcompensation bias (*i.e.*, medical device companies and physicians may, willfully or otherwise, establish arrangements that tend towards providing compensation for business referrals).

A reliable and comprehensive valuation approach should provide (i) an evaluation methodology that analyzes each parameter in an objective, consistent and repeatable way; (ii) a FMV outcome that encompasses all relevant parameters; and (iii) a FMV outcome that can be supported via *independent* market data. Such an approach to determine the FMV range for physician advisor / Thought Leader consultant arrangements can be based upon consideration of certain parameters, including: the extent of the services (*i.e.*, the time requirement); the nature of the specialty; the credentials/qualifications of the Thought Leader; and the specific services contemplated by the arrangement.

Under this approach, physician compensation data from national and regional surveys can become a starting point for further adjustment. This compensation data, considered across multiple years and adjusted to reflect payroll-related taxes and benefits, can be adjusted based on (i) the extent of Thought Leader time required; (ii) the specific requirements of the position; and (iii) the skills/experience of the specific physician Thought Leader specifically in terms of their acknowledged leadership in their specialty.

More specifically, in valuing a potential advisory arrangement between a medical device company and a physician, consideration can be given to the following factors based on the specific duties and responsibilities of the advisory position:

- Number of hours associated with each duty and/or responsibility.
- The specific duties & responsibilities of the position.
- The complexity of each duty and/or responsibility.
- Level of leadership required.
- Specific objectives and deliverables.
- Potential impact of Thought Leader/consultant on organizational and/or product success.

In addition, the following factors related to the physician’s qualifications can be considered:

- Educational credentials and specialized training.
- Professional certifications.
- Leadership experience.
- Academic appointments.

- Research experience and funding history.
- Invited presentations.
- Publication history.
- Other professional leadership activities / reputation in the healthcare community.

Each of these factors can be scored and weighted, also giving consideration to any interdependencies among the factors (*e.g.*, if the requirements of the services are rather basic, it may be unnecessary to engage a particularly well qualified physician). Care must also be exercised to insure that “double weighting” is not allowed in the case of any potential redundancy of qualifications. Provided that these factors are evaluated in a logical and consistent manner, an objective model can be developed to establish the FMV of physician consulting agreements.

In addition to the approach described above, a *direct market approach* can be utilized, provided that the reference market data is free from potential referral bias. The surest ways of identifying reliable market data are to consider physician compensation arrangements in settings which are known to be free of referral bias (*e.g.*, a medical director for a managed care organization) or to “cross walk” the arrangement to non-healthcare settings (*e.g.*, rates paid to comparably qualified professionals providing comparable services in other industries).

In summary, increased government scrutiny means there are many reasons to for device manufacturers to develop appropriate means of evidencing the FMV of their physician agreements, whether through internal resources or through the use of qualified independent third party appraisers.

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