

## Determining “Fair Market Value” for Physician Consulting Services: The New ‘Big Question’ for Life Sciences Companies

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### Background

Pharmaceutical and medical device manufacturers have frequently relied on physician “Thought Leaders” to provide subject-matter expertise, assistance with product-specific research and development, and patient or peer-to-peer education related to new product development. However, even though such arrangements are commonplace, the “consulting” agreements through which such services are provided have become the subject of increasing scrutiny by federal regulatory enforcement agencies. Such enforcement agencies include the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS), which, with the Department of Justice (DOJ), enforces Medicare fraud and abuse laws. Beginning with a “Special Fraud Alert” in 1994, the OIG has taken the position that compensation relationships between pharmaceutical manufacturers and physicians may implicate the federal Anti-Kickback Statute (AKS)<sup>1</sup> if compensation is more than nominal in value and exceeds the fair market value (FMV) of any legitimate service rendered to the payor by the physician.<sup>2</sup> The OIG has been clear that unless it can be substantiated as a market value payment for legitimate services, a physician’s receipt of remuneration from a product manufacturer may be scrutinized as a disguised incentive or reward for the recommendation or use of the company’s products.<sup>3</sup> The view of the OIG<sup>4</sup> and a common view among federal courts in several jurisdictions<sup>5</sup> is that notwithstanding that there may be other ostensibly legitimate purposes for which an arrangement has been entered, a compensation arrangement may violate the AKS if just *one purpose* of the arrangement is to induce or reward referrals.

Since 1994, the OIG and DOJ have become increasingly aggressive in investigating and pursuing AKS enforcement actions related to physician consulting contracts with the pharmaceutical and medical device industries. In 2007, four of the nation’s largest manufacturers of hip and knee implants made headlines after the United States Attorney for the District of New Jersey filed criminal complaints against each, charging them with conspiring to violate the AKS by entering “sham” consulting contracts with orthopedic surgeons, pursuant to which they paid tens to hundreds of



thousands of dollars to the physicians as inducements to use a particular product.<sup>6</sup> Each of the four companies entered Deferred Prosecution Agreements (DPAs) that required eighteen months of federal monitoring to assure compliance with certain requirements related to consulting agreements with physicians.<sup>7</sup> Each company also agreed to pay substantial fines—totaling \$311 million—to settle civil claims under the AKS and federal False Claims Act.<sup>8</sup> Additional costs were imposed on the companies by five-year Corporate Integrity Agreements (CIAs) that were part of the overall settlement agreements.<sup>9</sup> A fifth company (Stryker Orthopedics Inc.) voluntarily cooperated with the government and was able to enter a Non-Prosecution Agreement (NPA) and avoid criminal charges, but the NPA required Stryker to implement the same reforms imposed on the four companies with DPAs.<sup>10</sup> The DOJ Press Release announcing the settlements suggested that future federal investigations and prosecutions may be on the horizon,<sup>11</sup> and, indeed, subpoenas requesting records related to consulting agreements were issued to several additional companies soon after DOJ’s announcement of the 2007 settlements. Clearly, industry-physician consulting agreements have become a bull’s eye for federal AKS investigations.

### Fair Market Value and the AKS Safe Harbor for Personal Services Contracts

The most surefire way to assure that consulting agreements will escape (or at least withstand) federal scrutiny is to assure that the agreements comply with the requirements of one of the AKS “safe harbors.”<sup>12</sup> The most applicable safe harbor to physician consulting agreements is the “personal services” safe harbor,<sup>13</sup> which requires:

- The agreement is set out in writing and signed by the consultant and company engaging the consultant;
- The term of the agreement is at least one year;
- The agreement covers all of the services to be provided by the consultant and sets forth those duties with specificity;
- If services under the agreement will be provided on a periodic, sporadic, or part-time basis, the agreement sets forth the precise schedule and length of the time intervals, and the precise amount to be paid for each interval of work;
- The aggregate compensation paid to the consultant over the term of the agreement is set in advance, is consistent with FMV in arm's-length transactions, and is not determined in a manner that takes into account the volume of value of any referrals or business otherwise generated between the consultant and company for which payment may be made in whole or in part under federal healthcare programs;
- The services performed under the agreement do not involve the promotion or counseling of an activity or business arrangement that violates any state or federal law; and
- The aggregate services to be performed under the agreement do not exceed those that are reasonably necessary to accomplish the commercially reasonable purpose of the services.

Of all the requirements for complying with the personal services safe harbor, the one that probably causes the greatest head-scratching and consternation is the requirement *that the compensation is consistent with FMV in arm's-length transactions*. This is in part because even though the term “fair market value” has a generally accepted definition, this definition must be adapted to comport with the regulations that apply to healthcare transactions.

## Defining FMV in Healthcare Transactions

The term “fair market value” is generally defined as the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.<sup>14</sup>

For healthcare transactions, the generally accepted definition of FMV must be limited to comport with healthcare regulations, which suggest that FMV should be defined as the value in arm's-length transactions, consistent with the general market value, where “general market value” means the compensation that would be paid as a result of bona fide bargaining between well-informed parties to the transaction, when neither is otherwise in a position to generate business for the other party.<sup>15</sup>

The definition of “general market value” makes the determination of FMV for healthcare arrangements somewhat challenging—such as arrangements for physician consulting services—because compensation paid in the context of similar relationships (which frequently are relationships in which one party (i.e. the physician) is in a position to generate business for the other party

(i.e. a healthcare product manufacturer)) cannot be relied upon as determinative. The determination of FMV also may be complicated by the fact that the duties associated with physician consulting relationships can be quite diverse, which makes valid comparisons among the arrangements difficult. Valuers typically rely on one of three accepted approaches to determine the FMV of an asset:

- **The Market Approach**—defined by the International Glossary of Business Valuation Terms (International Glossary) as “a general way of determining a value indication of a business, business ownership interest, security, or intangible asset using one or more methods that convert anticipated economic benefits into a present single amount.”
- **The Cost Approach**—defined by the International Glossary as “a general way of determining a value indication of an individual asset by quantifying the amount of money required to replace the future service capability of that asset.” The Cost Approach is based upon the Principle of Substitution (i.e., the premise that a prudent individual will pay no more for a property than he/she would pay to acquire a substitute property with the same utility).
- **The Income Approach**—defined by the International Glossary as “a general way of determining a value indication . . . using one or more methods that compare the subject to similar businesses, business ownership interests, securities, or intangible assets that have been sold.” (Similar to a Cost Approach, a Market Approach also is based upon the Principle of Substitution).

For purposes of valuing service arrangements between healthcare product manufacturers and physicians who are in a position to generate referrals, the appropriate valuation approach must be carefully selected and applied to assure compliance with applicable healthcare laws and regulations. Generally, the Income Approach is not appropriate for valuing physician consulting arrangements since applicable healthcare regulations prohibit consideration of the value of possible referrals among the parties.<sup>16</sup> In addition, the Cost Approach may not be practical for valuing such arrangements because the employment of physicians who are established experts in their field to provide specific services for limited periods of time generally is not practical and, as such, reasonable substitutes to the planned physician consulting agreements may not exist. This means that, generally, a Market Approach is the most reasonable approach for determining the FMV of physician consulting services.

As noted previously, application of the Market Approach can be tricky because of the existence of tainted market values and the difficulties inherent in making comparisons among compensation arrangements that generally are quite diverse and may not make for perfect comparables. Accordingly, although a “direct” Market Approach based on comparison of compensation in “like” arrangements can be helpful for determining the FMV of compensation in physician consulting arrangements, it usually cannot be relied upon as determinative. A “direct” Market Approach will be most useful when the available benchmark data reflects compensation paid when referrals between the parties are unlikely. One may, for

example, look to compensation paid to physicians for directing specialty programs in a managed care organization, or one may cross-compare an arrangement to be valued to similar types of arrangements in non-healthcare settings (e.g. to compensation paid to comparably qualified professionals providing comparable services in industries other than healthcare).

In view of the challenges associated with identifying and collecting appropriate “direct” market data, our firm generally elects to utilize a modified Market Approach whereby physician salary survey data from multiple national and regional physician compensation surveys is used as a starting point for further adjustment. When employing this type of approach, we consider salary data gathered over the previous two years, adjust for payroll taxes and benefits, and then further adjust to reflect: (1) the specific requirements and nature of the duties associated with the consultant’s contemplated services; (2) the specific skills and unique qualifications that a specific physician candidate may bring to a contemplated consulting position; and (3) the extent of the time requirements that are associated with the contemplated position.<sup>17</sup> The adjustments are carefully made to assure that: (a) the adjusted compensation does not merely reflect “opportunity cost” to the physician to perform the services<sup>18</sup>; (b) there is proper consideration of whether the physician’s consulting duties are “clinical” or “administrative” in nature, and (c) of the differences between FMV for “clinical” and “administrative” services by a physician of the selected specialty.<sup>19</sup> By this method, we assure that our FMV assessment is both consistent with the definition of FMV as modified by federal healthcare regulations, and specific to the facts and circumstances of the arrangement being contemplated.

Specific factors we consider when employing our Market Approach methodology include:

- a. Factors specific to the consulting services, such as
  - Specific duties and responsibilities;
  - Specific objectives and deliverables; and
  - The expected or required allocation of time (hours) for each duty and/or responsibility
- b. Factors specific to the physician(s) who will provide the consulting services, such as:
  - Educational credentials and specialized training;
  - Professional certifications;
  - Leadership experience;
  - Academic appointments;
  - Research experience and funding history;
  - Invited presentations;
  - Publication history; and
  - Other professional leadership activities and reputation in the community.

Each of the factors is scored and weighted with consideration for any interdependence among the factors (consider that if the specific duties and responsibilities of the position are basic, it

may not be necessary to give significant weight to the physician’s research history, funding history, publication history, or other advanced qualifications). In our opinion, a valid and defensible FMV appraisal: (1) analyzes each factor in an objective, consistent, and reproducible manner; (2) takes into consideration all relevant factors; and (3) assures that, when appropriate direct market data is available, the outcome of an FMV appraisal is supported by the available direct market data.

## FAQs Regarding FMV Compensation for Physician Services to the Life Sciences Industry

1. *Corporate counsel and compliance officers frequently ask us whether FMV for physician consulting services is different (i.e., higher) for consulting services provided to pharmaceutical companies, medical device manufacturers, and other companies in the “life sciences” arena than for consulting services provided to academic institutions, hospitals, or government agencies. Is the FMV of physician services different when the services are provided to one industry versus another?*

Factually speaking, compensation for physician consulting services may be and often is higher for consulting services provided to the pharmaceutical and medical device industries than for consulting services that are provided to hospitals and academic medical centers. Interestingly, even the federal government seems to have acknowledged implicitly that FMV compensation *may* be higher for services provided to the pharmaceutical and device industries than for similarly categorized services provided to hospitals (we note that certain of the DPAs referenced earlier in this article require independent third party valuation for physician consultant compensation that exceeds \$500 per hour, while recent CIAs between the United States and certain providers of hospital services require independent third party opinions to establish FMV whenever physician compensation exceeds just \$150 per hour). However, if FMV is higher for physician services provided to product manufacturers, the reason is not simply that pharmaceutical and device companies are willing, able, and routinely do pay more for the same services as hospitals. Just as a driver cruising at 100 mph on the interstate is unlikely to avoid a citation by pointing out that many other cars drive 100 mph on the same stretch of road, the parties to a suspect consulting arrangement may not be protected from



federal prosecution and penalties merely because they are able to show that they are just doing what “everyone else” does. Rather, the reason that FMV compensation may be higher for services provided to product manufacturers is a function of the factors that distinguish these types of services from those provided to hospitals and academic institutions, including the nature of the objectives and deliverables associated with the services, and the specific qualifications of the physicians who will provide the services. Often, the physicians who are engaged to provide consulting services to the pharmaceutical and device industries are physicians who are at the top of their profession. There is precedent for pegging FMV at the high end of the compensation range for physicians who have complex duties and/or are at the top of their profession: In *United States ex rel. Villafane v. Solinger (Villafane II)*, for example, the U.S. District Court for the Western District of Kentucky indicated that it believed compensation in excess of the 75th percentile of national salary data is consistent with FMV for physicians who are highly qualified and have significant responsibility.<sup>20</sup>

2. *There are various times and circumstances when pharmaceutical and device companies engage physician consultants who are well known in a particular community, but not necessarily recognized as national or global experts in a field. Is FMV compensation for these “local” experts different from FMV compensation for national or global experts in a field?*

The FMV of physician consulting services is influenced by a variety of factors. As noted above, the specific qualifications of the physician who performs the services is one such factor. For purposes of determining the FMV of physician consulting services, we generally consider the following measures of a physician’s expertise and leadership in the relevant medical specialty:

- Educational credentials and specialized training
- Professional certifications
- Academic appointments
- Research experience and funding history
- Invited presentations
- Publication history
- Other professional leadership activities
- Recognition in the healthcare community

We have developed an algorithm whereby factors related to expertise and leadership (like other factors) are assigned a relative weighting, and each factor is analyzed in an objective, repeatable, and consistent way. When FMV is determined in this manner, the FMV range of consulting services provided by a physician who is considered a national or global expert in a specialty (and who probably has a relatively high number of publications and invited presentations, as well as history that includes one or more academic appointments and funded research projects) is reasonably higher than the FMV range for similar services that may be performed by a physician who is well respected in the community in which he or she practices, but who does not possess

qualifications to qualify him or her as a national or global expert in his her field.

## Conclusion

The FMV of physician consulting services to the life sciences industry (including pharmaceutical and medical companies) will vary with specific facts and circumstances. It is not an arbitrarily selected value, however, and should be carefully determined using a consistently applied methodology based on commercially reasonable criteria, and consistent with the definition of FMV as set forth in applicable healthcare regulations. When determined in this manner, compensation paid under physician consulting agreements may not be the same across all agreements, but should nonetheless meet the requirement of the AKS safe harbor for personal services contracts.

1 42 U.S.C. § 1320-7b.

2 *OIG Special Fraud Alert: Prescription Drug Marketing Schemes* (Issued Aug. 1994), republished at 59 Fed. Reg. 65372, 65376 (Dec. 19, 1994).

3 *Id.*

4 *Id.*

5 *See, e.g. United States v. Greber*, 760 F.2d 68, 69 (3d Cir. ), *cert denied*, 474 U.S. 988 (1985) (landmark case in which the Third Circuit adopted the “one purpose” test, stating “if one purpose of the payment was to induce future referrals,” the Medicare statute has been violated); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989) (upholding a jury instruction allowing conviction unless payment was “wholly and not incidentally attributable to the delivery of goods and services,” and stating that it does not matter if there are other purposes for a payment if one material purpose is to induce referrals); *Polk County v. Peters*, 800 F. Supp. 1451 (E.D. Tex. 1992) (holding that an agreement between a physician and hospital violated the anti-kickback statute because “the benefits extended to Defendant were, in part, an inducement . . . to refer patients the hospital . . .”).

6 *E.g. Artificial Joint Makers Settle Kickback Case*, N.Y. TIMES, Sept. 28, 2007; Press Release, United States Department of Justice, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007) (discussing government claims against Zimmer Inc.; Depuy Orthopedics Inc.; Biomet Inc.; Smith and Nephew Inc.; and Stryker Orthopedics Inc., and announcing that the U.S. Attorney’s Office for the District of New Jersey had negotiated DPAs with four of the five named companies, and an NPA with Stryker Orthopedics Inc.), available at [www.usdoj.gov/usao/nj/press.index.html](http://www.usdoj.gov/usao/nj/press.index.html).

7 United States Department of Justice, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007).

8 *Id.*

9 *Id.*

10 *Id.*

11 *Id.*

12 The AKS broadly proscribes any arrangement by which anyone knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program. Given the breadth of the statute, the government has promulgated certain “safe harbors” that set forth requirements for arrangements to avoid government action under the AKS. To fit within a “safe harbor” and be protected from government action, an arrangement must meet all the requirements of the designated safe harbor.

13 42 C.F.R. § 1001.952(d)

14 This is the definition of “fair market value” set forth in the International Glossary of Business Valuation Terms.

- 15 E.g. 42 C.F.R. § 411.351 (setting forth CMS' definition of FMV, to be applied with respect to physicians' referrals to healthcare entities with which they have financial relationships). The definition is also consistent with similar fair market value guidance related to the AKS and with the definition relied upon by the Internal Revenue Services. (See, e.g. Treas. Reg. § 53.4958 et seq.).
- 16 See, e.g. 42 C.F.R. § 411.351 (where CMS defines FMV for purposes of compliance with Stark, as follows: "the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals"); 42 C.F.R. § 411.357(d) (setting forth the AKS safe harbor for personal services agreements, and setting forth the requirement that the compensation paid over the term of the agreement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.).
- 17 We believe that this methodology is consistent with guidance from CMS regarding the calculation of FMV for physician services. In the Stark II, Phase II Final Rule, hourly payments to physicians for personal services were deemed to be FMV and to fit within a safe harbor if the hourly rate was calculated by averaging 50th percentile compensation values from either (1) local rates for emergency room physician services, or (2) at least four of six specifically enumerated physician salary surveys. In the Stark III, Phase III Regulations, CMS eliminated the safe harbor rate that it established in Phase II (72 Fed. Reg. 5105 (Sept. 5, 2007)) and indicated that the decision to eliminate the safe harbor was rooted in the fact that the prescribed methodology for determining the safe harbor rate *did not allow for consideration of particular facts and circumstances relating to a transaction, and therefore, was problematic.* (72 Fed. Reg. 5105 (Sept. 5, 2007)) CMS underscored that, going forward, "the appropriate method for determining fair market value for purpose of the [health care transaction] will depend on the nature of the transaction, its location, and other factors." (72 Fed. Reg. 5105 (Sept. 5, 2007)) CMS did affirm that "references to multiple, objective and independently published salary surveys remain a prudent practice for evaluating fair market value." (72 Fed. Reg. 5106 (Sept. 5, 2007)).
- 18 Government guidance with respect to methods for determining FMV for physician "administrative" services suggests that FMV does not equate to the "opportunity cost" to the physician to provide the administrative services rather than clinical services.
- 19 In commentary to the Phase III Regulations, CMS states that an hourly rate "may be used to compensate physicians for both clinical and administrative work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is the fair market value for the administrative work performed." (72 Fed. Reg. 51016). In later commentary, CMS states, "fair market value of administrative services may differ from the fair market value of clinical services." (72 Fed. Reg. 51016) With this commentary, CMS recognizes a distinction between FMV for a physician's clinical services and FMV for the same physician's administrative services, and advises that FMV for the same physician's clinical and administrative services may be different.
- 20 543 F. Supp. 2d 678 (W.D. Ky. 2008) (following an earlier decision in which the court ruled that satisfaction of the requirements for a Stark exception means that there is no AKS violation (See *United States ex rel. Villafane v. Solinger*, 457 F.Supp. 2d 743 (W.D. Ky. 2006)), the court considered whether the defendants met the requirements for the Academic Medical Center exception under Stark, and in doing so, considered whether compensation paid under the subject arrangement was "fair market value"; the court opined that compensation is FMV if it is consistent with national salary data, and may be FMV even if it is over the 75th percentile of national survey data if the physicians have strong qualifications and are at or near the top of their profession.).

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