Valuation of Physician Consultant Arrangements:
Ensuring Compliance within the Pharmaceutical Industry

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Overview

Facing criticism from governmental regulators, Wall Street, healthcare professionals and consumers, the pharmaceutical industry now finds itself in the center of a vortex of competing demands, escalating costs, expiring patents and increasing regulations. In the middle of this "perfect storm," demands are coming from all directions. Industry leaders, trying to make sense of constantly evolving regulatory mandates, find themselves facing some hard choices - focus their efforts on external "politics" or focus on their core business of developing new medications. Further compounding these problems are the skyrocketing costs of pharmaceuticals resulting in negative publicity, increasing competition and shareholder dissatisfaction. In addition, increasing levels of skepticism from government regulators regarding marketing practices, billing methodologies, research strategies and the industry's overall commitment to patient safety continues to cast a dark cloud over the entire industry.

The bottom line is that these are very difficult times for pharmaceutical manufacturers as they attempt to chart a steady course through a rather contentious environment. Arguably, notwithstanding the above, some of the most serious challenges facing pharmaceutical manufacturers are coming from government regulators as they attempt to deal with the negative impact of exponentially increasing drug costs on both state and federal funded healthcare programs. As these regulators hone in on the symbiotic relationship between pharmaceutical companies and the physicians who write prescriptions, it is inevitable that there will be heightened scrutiny of industry marketing practices that seem to promote the sale of newer and more costly drugs, while discouraging the sale of older, more time-tested and less expensive therapeutic alternatives. One outcome of this intensified focus is that regulators are becoming increasingly concerned that any type of payment to a healthcare professional could result in a conflict of interest by influencing their judgment and prescribing practices.

The Issues

As costs associated with developing new drugs rise into the stratosphere, pharmaceutical companies find themselves increasingly dependent on their marketing organizations to expand market share. The use of direct to consumer advertising has proven to be an extremely profitable approach, resulting in increasing numbers of consumers asking their physicians for specific advertised medications. However, as successful as this type of marketing has been, the bottom line is that physicians are still the keepers of the prescription pad; therefore, a significant amount of marketing dollars are focused on convincing physicians to write prescriptions for certain drugs.

Within this framework, physician education is of paramount importance. As new drug discoveries are made, physicians and other healthcare providers need to be educated about the unique properties and medical efficacy of these newer, potentially more effective (and often more costly) medications. However, increasing regulatory oversight is making it more difficult to capture the attention of busy healthcare professionals who are often bombarded with drug information.

Regulatory restrictions 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.*

Similarly, the federal physician self-referral ban (commonly referred to as the "Stark" law) prohibits financial relationships between entities and physicians who also refer patients to the entity for "designated health services" billed to federal healthcare programs. The Stark law may be triggered when (i) a physician, who has a financial relationship with a pharmaceutical company, (ii) prescribes an outpatient prescription drug (which is considered a "designated health service" under Stark) that (iii) is paid for by a federally funded program (*e.g.,* Medicare) and filled at a retail pharmacy affiliated with the pharmaceutical company. The bottom line is that federal law prohibits many types of payments to physicians who are in a position to purchase, prescribe, endorse or even recommend a product that is reimbursed under a federally funded healthcare program. As a result, the pharmaceutical industry is being forced into a very difficult position. On one hand, the industry has invested billions of dollars to deliver dramatic improvements in the treatment and prevention of life threatening and debilitative diseases. At the same time, however, companies are facing an increasing number of regulatory constraints which threaten to paralyze their efforts to successfully market their newly developed medications.

In an effort to inform physicians about newly developed medications, it is becoming increasingly common for pharmaceutical companies to engage the services of physician leaders who serve as advisors and consultants to other physicians practicing medicine in their targeted markets. Research has repeatedly shown that physicians are more willing to listen to and change their prescribing patterns after obtaining information regarding the therapeutic effectiveness of new medications from other well-credentialed physicians. As a result, pharmaceutical companies are now engaging legions of physician consultants and advisors to conduct promotional meetings and advocate on behalf of their products. In fact, payments to these physician advisors and consultants, which often total millions of dollars per year, have become routine marketing expenses for pharmaceutical companies.

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 substantial revenue from federal healthcare programs. As a result, relationships between pharmaceutical companies and physicians are becoming the focus of increased scrutiny from regulators. Questions are being raised with regard to the amount of money physician advisors and consultants are being paid, as well as possible conflicts of interest that may be inherent in the arrangement. In particular, a series of recent settlements between the government and medical device manufacturers, regarding payments to physician consultants, has triggered intensified efforts to ensure that physician relationships are fully compliant with the applicable laws.

Therefore, the question becomes: ***What is the best way to mitigate the apparent risk in relationships between physicians and pharmaceutical companies?*** Clearly, the Anti-Kickback and Stark laws are extremely broad, and could literally apply to virtually all physician-related marketing activities as well as to other non-promotional activities. Therefore, given the broad scope of the laws, certain safe harbors, exceptions and regulatory guidance have been provided in the statutes and further clarified and defined by the Office of Inspector General ("OIG") and the Centers for Medicare & Medicaid Services ("CMS"). With respect to the Stark law, all of the elements of at least one exception *must be satisfied* for an arrangement to withstand scrutiny. There are a number of potentially applicable exceptions; however, each of the most available exceptions for ensuring the compliance of advisory and consulting arrangements contains the same requirement of mandatory compliance with *fair market value*.

While Stark provides an exception for "bona fide employment arrangements," for the purposes of this discussion, we believe that the "personal service arrangements" exception is the most relevant because it is focused on protecting legitimate service arrangements (*e.g.*, advisory and consulting arrangements) with providers.[1] Under Stark, employment arrangements present the easiest way to comply with an exception as long as physicians are *bona fide* employees as defined by the Internal Revenue Code. However, since the appearance of independent advisors and consultants endorsing a new medication is far more compelling than an employed spokesperson, pharmaceutical organizations have rightly determined that most advisory or consulting arrangements be structured as independent contractor relationships. However, while these types of arrangements are more compelling to the external physician community, many pharmaceutical companies overlook the fact that these independent contractor relationships require compliance *across multiple elements* to fully satisfy the applicable

[1] Similar to the Stark exceptions, the Office of the Inspector General ("OIG") of the Department of Health and Human Services has developed certain "safe harbors" that protect certain specific arrangements from prosecution under the Federal Anti-Kickback statute. While compliance with safe harbors is not required, there are corresponding "safe harbors" for employment arrangements and personal services arrangements which are quite similar to the respective Stark exceptions.

requirements of the Stark exception. The "personal services arrangements" exception includes the following required elements:[2]

- Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement;
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of each arrangement is for at least one year;
- The compensation to be paid over the term of each arrangement 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;

Perhaps, the greatest impediment to achieving the requirements of the Stark exception involves issues related to establishing the *fair market value* ("FMV") compensation associated with these arrangements. Fortunately, regulators agree that by basing compensation for legitimate services provided on an applicable FMV rate (assuming that all of the other requirements listed above 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. The balance of our discussion will focus on key components of the FMV analysis.

Defining and Establishing Fair Market Value

It is generally accepted that the term "fair market value" is defined as the value in arm's-length transactions, consistent with the general market value. In the context of consulting or advisory arrangements between pharmaceutical 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.[3]

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[2] 42 CFR §411.357(d)

[3] 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.

Determining the FMV of compensation paid by a pharmaceutical company to a physician for advisory and/or consulting services is clearly important…..but as indicated above, is not easily established. In particular, the volume or value of referrals cannot be evaluated in the determination, and market data cannot be considered if the data represents other 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 valuators can use, and it makes FMV very difficult for pharmaceutical 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, a recent 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 do provide some helpful direction with respect to determining risky transactions. The settlement agreements reiterated that compensation for such arrangements must be at FMV, and further, certain settlements require the manufacturers to seek *independent third party opinions* to establish FMV anytime physician consultant compensation will exceed $500 per hour.[4]

Nevertheless, there is little valuation theory for an appraiser to rely upon in assessing these rather unique arrangements. In considering the primary valuation approaches, namely the cost, income and market approaches, an income approach can likely be eliminated because any attempt to utilize an income approach would give the appearance of considering the volume or value of business referrals between physicians and pharmaceutical organizations.

The determination of the FMV of advisory and/or consulting relationships between physicians and pharmaceutical 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. Further, advisory and consulting arrangements can be quite diverse, making comparisons among arrangements difficult. Finally, a potential drawback in looking to existing advisory and consulting arrangements as a basis for establishing FMV is that some of these relationships may be "*tainted,"* as they may contain an overcompensation bias (*i.e.*, pharmaceutical companies and physicians may, willfully or otherwise, establish arrangements that tend towards providing compensation for business referrals).

[4] 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.

Healthcare Appraisers ("HAI") believes that 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. Accordingly, HAI's proprietary methodology to determine the FMV range for physician advisor / thought leader consultant arrangements is based upon consideration of certain parameters, including: the extent of the services (*i.e.,* how many hours); the nature of the specialty; the credentials/qualifications of the thought leader; and the specific services contemplated by the arrangement.

HAI's proprietary approach to determining the FMV of physician advisor/consultant compensation is referred to as the Thought Leader Compensation Algorithm which is an analysis based upon the Cost and Market Approaches to valuation. As the starting point, this algorithm utilizes benchmark survey compensation data across multiple years, which is then adjusted to reflect payroll-related taxes and benefits. The algorithm makes a series of adjustments to the benchmark data 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.

As an example, if asked to value a potential advisory arrangement between a pharmaceutical company and a leading cardiologist, HAI would consider 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, HAI would consider factors related to the physician's qualifications, including:

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

Application of the algorithm's scoring methodology is based upon the establishment of relative weightings for the pertinent factors. In addition, the algorithm identifies interdependencies among the factors (*e.g.*, extent of time requirement vs. qualifications of thought leader), as well as any potential redundancy of qualifications.

HAI utilizes a direct Market Approach to provide validation of the values determined by the Thought Leader Compensation Algorithm. Within the framework of the market approach, HAI considers compensation arrangements that are free from referral bias; therefore, placing reliance upon "non-tainted" data.

In summary, increased government scrutiny means there are many reasons to obtain an independent third party fair market value assessment of arrangements between pharmaceutical companies and physician advisors/thought leaders/consultants. HAI's proprietary Thought Leader Compensation Algorithm provides an objective, consistent and repeatable methodology to determine the FMV these arrangements.

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