

## Fair Market Value

With no formal fair market value guidelines imposed by the government, how “fair” is it for pharma to play by the rules?

**E**li Lilly was one of the first major drug makers to voluntarily report payments to physicians. Today, other Big Pharmas are following suit, and it's no surprise. The Office of Inspector General (OIG) has hit medical device and pharmaceutical industries with multimillion dollar fines for violating fair market value standards; in fact, that's one main reason Daryl Johnson founded HealthCare Appraisers. Cultivating experience from work on the provider side of healthcare, a national medical oncology group, and practice management companies, Johnson started his own specialized healthcare consulting firm. The company has performed many projects for companies within the life sciences industry, and it has become clear that fair market value issues are similar for both the hospital and the life sciences industries.

**Since there is no government-approved standard to determine fair market value, what can industry rely on?**

**Daryl:** Well, that's really one of the major problems. There was a brief period when the federal government created Safe Harbor rates for hourly compensation arrangements with physicians, but those tended to be very low. They were of limited usefulness to companies making payments to physicians, and subsequently, the federal government rescinded them.

Pharmaceutical companies face the requirement of complying with the fair market standard, but the government sets forth very limited guidance in terms of how fair market value should be determined. However, a key area of federal guidance in the area of fair market value is the concept of not placing reliance on market rates. There is specific guidance from the government that cautions companies not to rely on values that may represent an overcompensation bias.

**Ann:** I think pharmaceutical companies are looking at their physician relationships in very different ways than they did previously. For example, typically physicians would ask for the level of compensation they wanted, often based on what they heard other physicians were being compensated, and the pharmaceutical companies generally paid the requested amount in order to secure their services.

**What has changed since the fair market value yardstick was implemented? Have companies reorganized to keep compliant?**

**Ann:** As the government continues to increase its scrutiny of physician compensation arrangements in the life sciences, we are definitely seeing changes in how compensation arrangements are structured and paid. The idea of transparency, as a way to mitigate risk, is beginning to take hold as increasing numbers

of pharmaceutical companies are posting what they pay physicians on their websites. We have also seen an increase in the number of life sciences companies that are seeking independent third party fair market value assessments of their physician compensation arrangements.

**Is there a “best” way to measure value?**

**Daryl:** The best approach is to rely on the knowledge base of fair market value that exists in other settings. “Fair market value” is a term of art. It is generally defined as a value negotiated at arm's length between a hypothetical willing buyer and a hypothetical willing seller. The IRS has very clear guidelines on methodologies that are acceptable to the IRS when valuing businesses. Those standards and the fair market value body of knowledge can generally be cross-walked to the determination of the fair market value of a compensation arrangement. For example, with traditional business valuations the primary approaches are cost, income, and market. Likewise, in a compensation valuation setting, consideration can be given to the same three valuation approaches so that one can use the guidelines and the techniques that were developed in business valuations to apply to compensation valuation.

**How have thought leaders responded to these changes? Has it directly impacted relationships with doctors?**

**Ann:** I think it's reasonable to assume that physician thought leaders are not necessarily happy with the changes because these changes tend to limit their compensation. In today's environment, the government is looking over everyone's shoulder; therefore, pharmaceutical companies often have to



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say, "We can't pay you any more than X amount." Oftentimes, this means the physician is asked to accept a level of compensation that is below what he or she thinks his or her time is worth. Unfortunately, it's often very difficult to explain to a physician that the compensation he or she receives for making a presentation on behalf of a pharmaceutical company may not be equal to what he or she earns while performing a clinical procedure. The reality is that the days of compensating physician thought leaders at whatever rate they want to be paid... are pretty much over.

**Daryl:** Among guidance from the government, I mentioned that reliance on market values might contain an over-compensation bias. Another specific area relates to the issue of opportunity cost. The government is pointing out that the value of clinical services and the value of administrative services may not be the same, so that's a key aspect of guidance in establishing fair market value.

**Ann:** The fact remains that pharmaceutical companies need to secure the services of physicians because physicians tend to listen to other physicians more than they would to a non-physician. Therefore, pharmaceutical companies are faced with a daunting task, they need to continue to engage the services of physicians to educate other physicians, while complying with a regulatory environment that basically says you can't pay too much ... but, doesn't actually provide guidance on how to determine what too much is.

One of the questions we often encounter is how to determine the FMV compensation for physician travel time? We've had some interesting discussions in our office involving the value that should be applied to travel time. One of the key issues we wrestle with is: Should travel time be compensated at the same level as the time spent performing the services the physician was contracted to provide (e.g., consulting, presenting, etc.)? We tend to not value travel time at the same rate as the actual services the physician was engaged to perform. However, with that being said, travel

time needs to be part of the compensated calculation because it does require the physician's time.

**Where are you seeing the most errors committed? And, in terms of documentation, what should be used to demonstrate compliance?**

**Daryl:** Errors are arising in several respects. One is the lack of appropriate attention to documentation by the pharmaceutical company in supporting how certain rates were arrived at. Another common error is simply relying on present market values in the industry that may be unrealistically high. A third error is the inappropriate assumption that the process of an arms-length negotiation, or meeting the demands of physicians, constitutes fair market value.

It's really left up to industry to determine the extent of documentation that is believed appropriate. The federal government, except in cases of mandatory compliance with corporate integrity agreements, doesn't require that compensation payable to physicians be supported by an independent third-party opinion. If pharmaceutical companies internally determine fair market value, then, like an independent consultant, they need to develop a compelling argument for the basis of their information and the basis of their conclusions. They also must be ready to have this information available, when and if it is necessary, to demonstrate to the government that they believe that what they are paying physicians is within fair market value.

**How is physician compensation assessed in fair market value calculations? Are there tiers?**

**Ann:** Yes, we believe that different physician requirements, in terms of expertise and experience, as well as differing responsibilities in terms of the tasks to be performed, will have an impact on the fair market value of the compensation. For example, within a marketing framework, if the pharmaceutical company is looking for someone who can provide leadership on a national level, the physician selected to perform the function

should probably have a national reputation. Similarly, if the pharmaceutical company is looking for an advisor who has very specific expertise and experience, then only a physician with that particular skill set would be appropriate choice.

We consider a whole host of variables as part of our approach to determining the fair market value of the compensation relationships. For example, within the framework of our analysis, we scrutinize the specific requirements of the position as well as perform an in depth analysis of the identified physician's expertise and experience. However, we recognize that many arrangements between pharmaceutical companies and physicians do not require such an in depth level of scrutiny. As a result, we have created a tool that can be used by pharmaceutical and medical device companies in determining the FMV of certain physician compensation arrangements. This tool has great value to companies that engage many similarly experienced and credentialed physicians to perform similar types of tasks.

**How should a pharmaceutical company deal with a physician who disagrees with the compensation range you indicate as the fair market value?**

**Ann:** If a physician decides not to accept the level of compensation offered by the pharmaceutical or medical device company, then it's up to the company to determine the level of risk it is willing to assume. Since the government's regulators have not established approved compensation ranges, or even the methodologies they want used to determine these ranges, it is not a clearly defined choice. We have seen some significant penalties handed down by the government, so in the absence of well defined guidelines it's probably a good idea to use a defensible methodology that does not consider the volume or value of referrals, to determine physician compensation. Clearly, the risk may even be lower when that defensible methodology comes from an independent source. **PE**