

Rx COMPLIANCE REPORT

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Special supplement: Fair market value

Demystifying Fair Market Value Determination: A Proposed Methodology for Determining FMV of Physician Honoraria

By Andy Bender, Tamsen deRaaf, and Nicole Gray

In its final guidance for drug manufacturers, the Office of Inspector General of the Department of Health and Human Services (OIG) declares that pharmaceutical manufacturers must compensate speakers and consultants at “fair market value” (FMV) in order to avoid the appearance of offering inducements to change prescribing behavior and to actively discourage “quid pro quo” relationships in general. This is the government’s latest attempt at reconciling two potentially opposing interests in the pharmaceutical industry.

On one hand, pharmaceutical firms need insight from physicians to enhance and refine their treatments, and, consequently, pay physicians for their time and service. On the other hand, patients require that their physicians provide high quality, unbiased treatment and prescription recommendations. To achieve both of these important goals, pharmaceutical firms must not compensate physicians at inflated levels that may bias, or appear to bias, treatment decisions. In other words, physicians must be compensated for their services to pharmaceutical firms at fair market value.

While this may seem simple, the question remains: What is fair market value for a physician’s time and service? Although the OIG created the FMV mandate, it has not provided clear guidelines for making such payment determinations. The purpose of this article is to recommend a methodology for bridging the gap,

providing a framework for fair market value determination that is consistent, transparent, and simple.

The IRS defines fair market value as “the price of a service between a willing buyer and willing seller,

neither being under any compulsion to buy or sell and both having reasonable knowledge of the relevant facts.”

Essentially, fair market value is the result of an arm’s length transaction between unrelated parties. Although this definition of FMV is straight-forward, determining FMV for the services of pharmaceutical speakers and consultants can be a complex and

confusing process as the parties are clearly related. Physicians are responsible for prescribing the products of pharmaceutical firms, and, as a result, they generate sales for these firms.

Pharmaceutical companies’ payments to physicians will continue to be a controversial topic, but by making a commitment to defining and compensating physicians at fair market value, companies can significantly reduce their compliance risk.

When physicians are hired by pharmaceutical firms to provide speaking and consulting services or are given funds by these firms to conduct research as independent investigators, a potential conflict of interest arises. In certain situations, a prosecutor could make the case that a pharmaceutical firm is using physician compensation for speaking and consulting services or research funding to induce those physicians to prescribe more of their products.

Pharmaceutical firms must develop a consistent and transparent process for determining FMV of honoraria. One intuitive method for FMV determination is the use of an industry-wide pharmaceutical speaker and consultant compensation survey. By querying pharmaceutical companies about their physician-consultant compensation practices and compiling the results, the industry could provide a baseline reference for FMV.

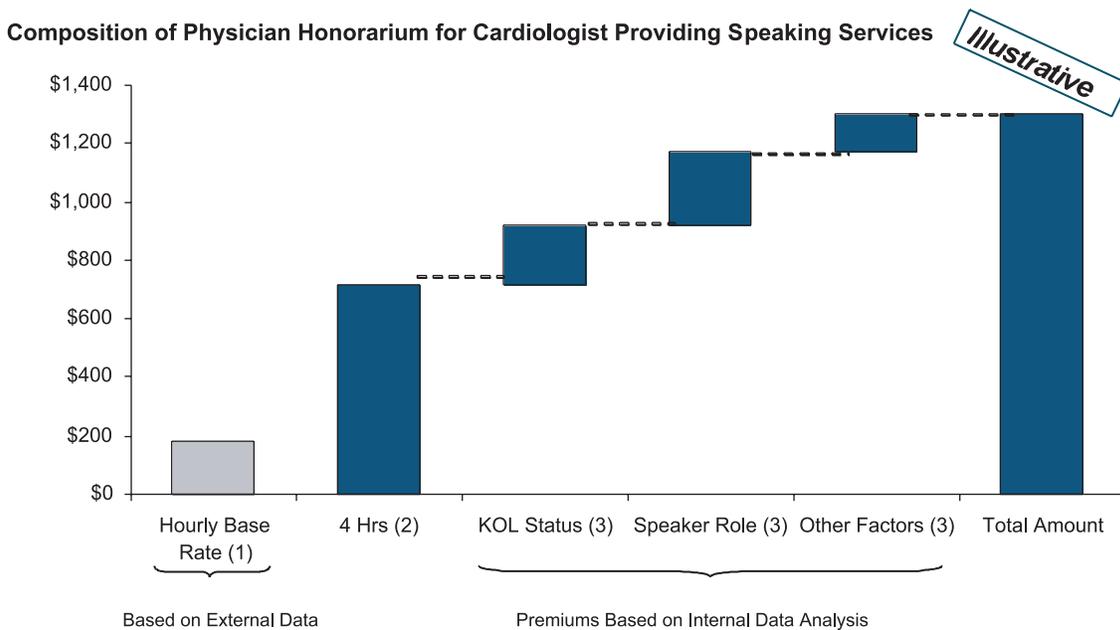
Although this method may seem intuitively logical, it has significant shortcomings. The survey results would not be based on “arm’s length” transactions between unrelated parties. After all, it is possible that the entire industry has been paying rates that are above fair market value because the only buyers in the market (pharmaceutical firms) have had an incentive to

overpay the sellers (physicians).

In addition, even if these data were captured, it would be hard to compare. For example, if two pharmaceutical companies are paying similar fees in exchange for speaker/consulting services from a cardiologist, head-to-head comparisons might be misleading as these seemingly similar payments could be for two completely different services; for example, one is paying for the services of the chair of an advisory board, and the other payment might be to a general participant.

The Recommended Approach

The authors have developed an approach to valuing physician consultant/speaker services that avoids the shortcomings described above. This approach utilizes both external data from physician compensation studies and internal pharmaceutical company data on honoraria. The external data provides an objective baseline for physician hourly compensation, while the internal company data is used to determine any value-added premiums that should be added to the baseline to arrive at the FMV for a physician’s speaking or consulting services. The figure below illustrates the way in which the process arrives at a final value.



- (1) Based on national salary surveys.
- (2) Amount of time physician is retained for service.
- (3) Based on data obtained from marketing personnel, sales teams, and medical communications companies.

Step 1. Determine an hourly base rate: The labor market for physician medical services is a good starting point when determining physician compensation. It is the largest and most liquid market for buyers and sellers of physicians' time, and is therefore the best initial proxy for FMV. Several national salary surveys published by consulting and recruiting firms provide data on physician compensation by specialty, geography, and years of experience. The authors have identified 6 high-quality physician salary surveys and suggest that data from 2 to 4 surveys be incorporated into the analysis in order to obtain representative results.

The use of multiple surveys is recommended due to variability in physician wages by employer type. Many surveys focus on one type (e.g., private practice, hospital, etc.) and may not be individually representative of the entire labor market. The outcome of this data analysis is an hourly rate of compensation for each physician specialty. As expected, hourly compensation varies dramatically across specialties with diagnostic radiologists at the top of the range earning nearly \$250 per hour and pediatricians at the low end earning approximately \$100 per hour. This hourly rate will be multiplied by the number of hours a physician is hired to provide services, resulting in the base compensation for that physician.

Step 2. Collect Internal Information: Once the baseline for FMV is established, internal company data can be analyzed to determine the value-added premiums that should be paid for the unique characteristics of the pharmaceutical service being provided and the physician providing that service. For example, different premiums would be added for the provision of speaking services versus participation in an advisory board. Likewise, different premiums would be added for Key Opinion Leader (KOL) status and physician experience level.

The internal data can be collected through interviewing marketing personnel, sales teams, and medical communications companies using "honorarium questionnaires," surveys designed to gain insight into the physician compensation process. Insight from these knowledgeable participants complements the external data analysis and allows the company to create a comprehensive picture of the way in which physicians' honoraria are determined. Including internal sales and marketing personnel, as

well as external vendors, in the process is also important for obtaining buy-in for this new compensation process and for promoting understanding and acceptance of FMV-based transactions.

Step 3. Creating an FMV Formula: The final step in this process is combining the internal and external data, which will help the company arrive at a definitive formula for FMV. The formula will be designed to value the influence of different factors affecting physician honoraria so a product manager or compliance director can determine honoraria based on a number of pre-set parameters. Examples of these parameters include: type of event, physician role, physician specialty, and physician KOL status. Ideally, to ensure the FMV formula is objective and reflects prevailing ethical norms, a third party should be retained to determine the FMV formula.

Data collection and retention

This approach to determining FMV can be challenging, largely because the breadth of the analysis depends upon available data. While external data is usually easy to obtain, securing internal data may require preparation and persistence. It is important to be clear what information you are requesting and the desired format for that information. Coordinating data collection efforts from internal personnel and vendors may involve substantial effort; however, once a methodology for collecting and analyzing data is established, it can be developed into an effective system that will serve the company into the future.

Results

Ultimately, the formula for calculating FMV can be used to create user-friendly tools for marketers and vendors who determine physician compensation for speaking and consulting services. These tools can range in complexity from a simple rate sheet to a complex honorarium calculator. The complexity of the tools will increase as additional premiums (from Step 2) are incorporated. For example, a simple rate sheet may include only one or two key premiums, while a calculator might incorporate as many as five to seven premiums.

Well-designed tools will compute a range of appropriate honoraria, and the type of tool used will

depend on the availability of internal data to determine the premiums, as well as the amount of flexibility a company wants to give its sales and marketing staff in determining honoraria. Additionally, these tools may be integrated into a firm's contract management system to ensure consistency of the process and the creation of an auditable decision trail.

Ongoing Process

Maintaining honoraria policies is an ongoing process. Honoraria rates should be adjusted each year to compensate for inflation and changing market dynamics. In addition, pharmaceutical companies will need to implement methods for ensuring that internal personnel and vendors adhere to the established policies. Maintaining records of physician payments will allow companies to monitor over time the physician compensation process and view changes in physician payments.

The ability to review how often a physician has been engaged and paid for services is also critical. Most companies are currently embarking on initiatives aimed at answering these questions by developing a comprehensive picture of a physician's compensation across all functions, including marketing, research, and CME.

Adopting the FMV determination methodology described in this article has many advantages. The external/internal approach to FMV analysis is a relatively quick and efficient way to develop a consistent and transparent methodology for determining FMV that meets OIG requirements. Moreover, the use of both external and internal data provides objectivity while ensuring that the FMV determination reflects the unique nature of the speaking and consulting services being provided.

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Implementing An Honoraria Policy

In addition to using tools for calculating physician compensation, companies also need to provide general policies that are commensurate with compliance objectives for honoraria. For example, the policy would set limits on the number of programs or events within a given year in which a physician could participate, as well as a limit on the total value of honoraria a physician could receive in a given year. Setting limits is important, as attempted inducement might seem likely if honoraria were to reach a certain percentage of a physician's total compensation. Some companies set limits of \$50,000 or 50 speaking engagements; others set limits of \$20,000 or 20 speaking engagements.

The honoraria policy should also state the maximum number of physicians a company could retain for speaking and consulting services, and, conversely, the minimum number of speaking assignments required for each speaker trained. The appropriate policy depends on a number of factors, many of them specific to the company in question. However it is likely an industry standard will emerge in coming years.