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Pharmaceutical Executive

Pharma pays doctors hundreds of millions of dollars each year to tell colleagues about drugs. Warning of potential fraud and abuse, OIG set guidelines for fees. But even compliant companies may face tough lawsuits unless they can prove they pay

FAIR MARKET VALUE for Physician Consultants

BY FRED EATON AND YORAM LEVY

Large pharmaceutical companies pay millions of dollars a year to doctors who, in after-dinner speeches and other forums, tell other doctors about their products. Such payments to consultants and advisors have become routine marketing expenses. But they may soon come under close scrutiny from the Office of the Inspector General (OIG), which sees in promotional speaking and advisory services a “high potential for fraud and abuse,” according to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers.

As part of these guidelines, released in 2003, OIG issued specific rules governing consultant and advisor compensation. Most of these requirements are straightforward and easy to follow. Consultants have to provide a legitimately needed service, under a written agreement that is docu-

mented, before they are paid. But a final condition—that doctors must be paid fair market value (FMV)—creates a real challenge for most pharma companies. Not because anyone resists complying with the new rules, but because the guidelines themselves are so fuzzy that companies may be unable to follow them—or equally troublesome, unable to build a convincing case that they did.

Companies and prosecutors may agree that FMV compensation eliminates excessive payments and reduces the apparent conflict of interest in paying doctors for services they provide to pharmaceutical companies. But without a definition of FMV and a procedure for determining it, a pharma company could end up facing a federal prosecutor whose views define the concept of FMV in court.

This problem is not destined to go away anytime soon. Research shows that doctors are most strongly influenced to prescribe by other doctors. The number of promotional meetings has quadrupled in the last six years, to nearly 240,000, according to Verispan. That number will easily exceed a quarter million this year. Since 2003, six top pharmaceutical firms have signed corporate integrity agreements with OIG, several of which specifically address consultant contracting. OIG clearly believes that these marketing practices create significant compliance risks.

Here are a few scenarios that might require explanation under the new guidelines:

- » For the second or third time over the past five years, a renowned liver specialist who has spoken for ABC Pharma says that competing firms are offering higher rates for promotional talks. He requests and receives yet another hefty fee increase. Can ABC pay more to keep a valued consultant without running afoul of OIG?
- » Two different physicians make essentially the same presentation about hypertension, in which they discuss a company's medication and treatment plan. One of the doctors is a primary care physician, while the other is a cardiologist, who demands and receives nearly double the fee of the primary care doctor. Is this appropriate? Could the higher fee be characterized as a kickback?
- » Two cardiologists are paid to give similar promotional talks for the same company. One is paid \$1,000; the other is paid \$1,500. Can the company minimize the risk of the extra \$500 being viewed as a kickback?

Over the past five or six years, many pharmaceutical companies have added to their pool of consultants and advisors, often without codifying pay rates. Most companies believe the rates they pay for doctors' services are similar to those paid by other companies. Unfortunately, under the new, fuzzy OIG guidelines, that does not necessarily mean they are paying FMV.

Fair Market Value: Keys to Compliance

Needs assessments: This vital step in the contracting process makes the business case for conducting a particular activity with a particular consultant or speaker. The information collected can include unusual characteristics of the activity involved, or unusual credentials of the consultant.

Consultant selection: Consultant selection issues arise in two different areas of the contracting process. First, companies must ensure that they have an appropriate mix of consultants in their pools of advisors (e.g., geography, expertise, specialties, etc.). Second, and potentially more critical, companies must select the appropriate consultants for particular activities. Does the objective of a particular activity justify hiring the most knowledgeable expert in a field? Or can the goal be achieved by choosing consultants of somewhat lesser stature who command lower fees?

Substantiation of "expert" (KOL) status: Many companies have multiple fee schedules based on doctors' level of expertise or recognition. While it is appropriate to pay for expertise, the challenge most companies face is developing objective standards and processes for determining "expert" status to justify premiums above the standard FMV rates.

Limits on total annual compensation for individual consultants and/or speakers:

Both maximum and minimum payment levels may be considered in a FMV policy. While individual payments to a particular healthcare professional may all be made at FMV, the cumulative annual payment level can raise both compliance and public relations risks. At what point do the cumulative fees paid to a consultant distort his or her independence and objectivity? Few companies want to approach any grey areas in public perception.

Managing third-party service providers: Many pharmaceutical companies contract large portions of their consulting and speaking needs through meeting-planning vendors. Customers must develop procedures to ensure that such service providers are in compliance with companies' policies, and that they adhere to specific rate schedules.

Compliance tracking and data retention: Centralized management of FMV schedules and contracting is insufficient without a tracking process and a data-retention procedure that covers all internal and external dealings with consultants and speakers. For each individual speaker and advisor deployed, the company must maintain records of all services rendered and every payment received. In addition to the improvements that come with analyzing the accumulated data, the tracking system creates an audit trail, which is essential to fully complying with OIG guidelines.

The government does not provide any guidance on how firms should calculate FMV. This leaves government prosecutors with considerable latitude in developing theories about excessive payments. They may argue, for instance, that pharmaceutical companies use the fees for these advisory and

speaking services to influence doctors' treatment decisions and prescribing behavior.

Prosecutors could view high consultant fees as encouraging a "quid pro quo" relationship between medical professionals and pharmaceutical companies. Historical prescription data identi-

fies a company's highest-prescribing physicians, who are in some cases the most sought-after consultants. But from the point of view of a prosecutor free to theorize, they may also be likely candidates for bribes or kickbacks.

Rather than end up on the defensive, facing OIG's requirements armed only with good intentions and vague recollections of payment decisions, companies need to develop a consistent and transparent methodology for determining FMV for services provided by healthcare professionals.

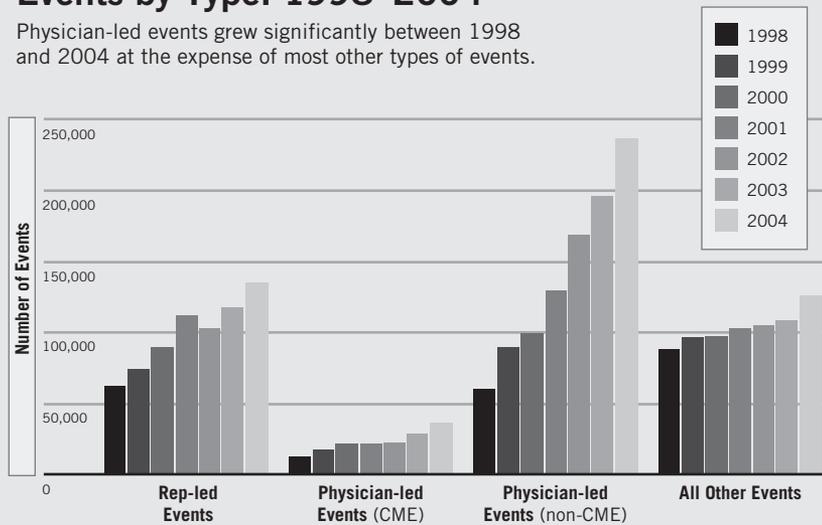
The challenge is coming up with that theory. To begin the process, a pharmaceutical company might look to the IRS, which has defined FMV as "the price of a service between a willing buyer and a willing seller, neither being under any compulsion to buy or sell and both having a reasonable knowledge of the relevant facts." While this definition appears simple, it does not go far toward determining a pharmaceutical company's proper fee for consulting doctors.

There are other methods. One intuitive method that doesn't work: conducting a survey of the historical rates paid to doctors by pharmaceutical companies. Unfortunately, such survey results may not provide real market rates, since the overall industry standard of payments for consulting and speaking engagements may have been inflated over the past several years. More important, relying solely on a broad survey of historical payments may not have the granularity appropriate to an individual company's compensation decisions. If a company needs to hire a recognized expert, it may have to pay a premium. Finally, it is difficult to compare payments when there are so many factors, such as specialty, tenure, type of services, and level of involvement.

A better way to look at FMV: Use unbiased market information. Combining external data from national physician-compensation surveys with internal information from an individual pharmaceutical company can generate a rate schedule for the time and expertise of doctors. There are three phases in the process of calculating this sched-

Events by Type: 1998–2004

Physician-led events grew significantly between 1998 and 2004 at the expense of most other types of events.



An audit trail for consultant payments stands up against charges from a prosecutor.

ule. The result is a defensible, procedural definition of FMV that a company can present as an alternative to a FMV theory presented by a federal prosecutor.

I. Defining hourly base rates

Several research companies and medical associations survey the labor market, so it is possible to compile several surveys and generate an integrated view of annual physician compensation by location and specialty. The analysis of compensation surveys can provide a range of annual or hourly base-compensation rates that includes an upper value, a lower value, and a central tendency value, such as mean or median. Once an initial base rate has been determined, additional adjustments may be required to reflect differences between salaried employment and independent consulting (e.g., fringe benefits). Including these adjustments provides an all-inclusive annual and hourly

compensation rate for doctors.

II. Determining activity base rates

Here the focus shifts to obtaining internal company information. Analyzing interviews, internal surveys, physician questionnaires, and other data reveals the scope of current and future business requirements. The internal analysis specifically identifies activities performed by doctors and the time and effort required to accomplish them.

This information is essential to determining the FMV for compensating different types of activities. It also allows for compensation premiums, which can be added to the base rate for various roles. For example, different premiums can be added for leading an advisory board versus facilitating a speaker-training event. Probably the most important adjustment to the base rate is the key opinion leader (KOL) or expert premium. This premium compensates a consultant for his or her higher level of expertise and experience in a field.

Other premium adjustments may be provided for preparation or travel time, if those factors prove substantial.

III. Create an FMV Rate Schedule

A schedule of FMV rates for a firm's key speaking and consulting activities may be thought of as a calculator with preset parameters to accommodate possible business variations in a consistent and predictable manner. The

OIG published seven elements of an effective compliance program:

- 1 Implement written policies and procedures
- 2 Designate a compliance officer and compliance committee
- 3 Conduct training and education
- 4 Develop effective lines of communication
- 5 Conduct internal monitoring and auditing
- 6 Enforce standards through well-publicized disciplinary guidelines
- 7 Respond promptly to detected problems, and undertake corrective action

OIG requires payments to meet five conditions:

- 1 Written agreement
- 2 Legitimate need
- 3 Provision of services
- 4 FMV compensation
- 5 Documented prior to payment

FMV calculator provides a practical, easy-to-use, objective platform for determining FMV fees for consultants and speakers. It blends the external information analyzed in phase one with the internal information gathered in phase two. The calculator includes premium adjustments for activities, roles, specialties, and levels of effort required.

In addition to a company-wide rate schedule, which is likely to accommodate most payments for consulting and advisory services, companies will need to establish a review committee to manage the process and deal with inevitable exceptions. For example, a physician with unique experience may demand a custom FMV appraisal. In such a case, the review committee provides critical controls to ensure compliance and, if appropriate, approve a premium payment with

proper justification and documentation.

With these tools in hand, companies can confront the problems posed by the scenarios mentioned on page 12.

In the first scenario, ABC Pharma could convene its committee and discuss justifications for raising the rates of the liver specialist who seeks a raise.

In the second case, the calculator itself would account for the disparity between the fees of the primary-care doctor and the cardiologist on the basis of the different base rates for their respective specialties.

The third scenario highlights a problem that is only partly about FMV.

Paying the cardiologist a higher rate may be justified by the work involved. However, in practice, consistency and transparency in payments is as important as the rates themselves. If the work involved is virtually identical and the expertise of the two physicians is also the same, then they need to be paid the same rate.

The company can either raise the rate of the lower-paid consultant or begin reducing the rate of the more highly-paid consultant.

Together, the calculator and review committee represent a quantifiable, procedural response to the inquiries of an OIG investigator or the charges of a prosecutor. From a compliance standpoint, that is the goal: In the absence of federal rules on how to calculate FMV, pharmaceutical companies must be prepared to match an OIG take on compensation with a well-reasoned version of their own. 

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Step-by-Step FMV Determination

FMV Calculation*

Step 1: Define Hourly Base Rate

Hourly base rate for an oncologist is \$190

\$190/hour

Add value of benefits and other adjustments to get all-inclusive hourly rate

\$190 x 1.30 = \$247

Step 2: Define Activity Rate

Multiply number of hours by hourly rate (Example: 3 hours)

3 hours x \$247 = \$741

Step 3: Add Premiums

Expert-status premium (KOL)

+ \$500.00

Preparation-time premium (2 hours)

+ \$494.00

Travel-time premium (3 hours at 50% of all-inclusive base rate)

+ \$370.50

*Illustrative, numbers do not necessarily reflect actual rates

FMV = \$2,105.50

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