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Demystifying Fair Market Value ^{HS}

Ask any biopharmaceutical sponsor or investigative site what the term “fair market value” (FMV) means, and you will receive a myriad of explanations and differing opinions on the implications and concerns as FMV pertains to clinical trial budget negotiations. Confusion exists over the definition of FMV, how this affects sponsors and sites, and the implications of noncompliance, among other things. Though not intended to represent official legal or regulatory advice, this article attempts to demystify some basic factors related to FMV principles, with the goal of fostering improved understanding and dialogue on such issues as:

- What does FMV mean?
- Why is it of importance/concern to the pharmaceutical industry?
- How is it determined?
- What do sponsors need to consider to ensure they are in compliance?
- What can investigative sites do to support the budget negotiation process in light of FMV guidelines?

Background

The business of clinical trials is rooted in the relationship that begins with a protocol and a budget to compensate investigators and institutions for their efforts to execute a study. Over the past several years, the development of the per-patient grant and associated costs has evolved into a process that undergoes great scrutiny and instills fear in many sponsors. This fear is born out of pressure from two key stakeholders: the investigators or associated institutions and various regulatory authorities. On the one hand, investigative sites have an interest in ensuring they are fairly compensated for their effort to conduct the trial and, likewise, sponsors want to make sure that the proposed site budgets are palatable so that the sites are engaged in the trial. On the other hand, sponsors must balance this with an approach that ensures the fees paid to the investigators are reasonable and in line with FMV.

Though not a new concept to the clinical research industry *per se*, FMV is a growing hot button issue for biopharmaceutical and device sponsors and investigative sites in today’s competitive and cost-constrained environment. Because there is a lack of clarity and understanding on many aspects of FMV, different parties have different interpretations of the “letter and spirit” of FMV guidelines. The result is that budget negotiations are protracted, study startup

^{HS} Home Study article

LEARNING OBJECTIVE

At the conclusion of this course, participants should be able to describe the concept of fair market value.

DISCLOSURES

Beth D. Harper, MBA, discloses that she is an employee and stock shareholder of Center-phase Solutions. Kevin T. Williams, MBA, MS, discloses that he is an employee and stock shareholder of Clinical Financial Services, LLC.

timelines are delayed, and, in some cases, successful agreement on investigative site budgets cannot be achieved. Although the principles of FMV, anti-corruption, and antibribery rules and regulations apply globally, due to space limitations, this article focuses primarily on the factors influencing FMV determination and compliance requirements in the United States.

Where Did the Concept of FMV Come From and What Does it Mean?

Understanding FMV requires us to go back to the 2003 Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers from the U.S. Department of Health and

that tries to define the appropriateness of payments when there are conflicting or at least multiple justifications for those payments.”²

The word “fair,” in and of itself, conjures up different interpretations. “Fair market value is not an average market value or an equal market value,” notes Alicia Bucko, DO, JD, of Academic Dermatology Associates in Albuquerque, N.M. “Think about paying for a car,” she continues. “We all know in our heart of hearts what a fair price should be, and we have an idea of whether we are being taken advantage of. But translating that feeling into raw numbers for the purpose of negotiating a clinical trial budget is the challenge.” Many industry professionals, however, agree that, from an enforcement per-

pany, and not just an opportunity to influence prescribers.²

Factors Influencing FMV Practices

Beyond the OIG report, it is important to consider all of the various factors influencing FMV practices (see Figure 2). Selected examples include federal and state regulations, as well as professional codes of conduct. The federal Anti-Kickback Statute, Stark Laws (42 *Code of Federal Regulations* Parts 411 and 424 regarding physician referrals), and the Physician Payment Sunshine Act are a few of the more noteworthy regulations affecting FMV practices.

A detailed discussion of the various federal and state regulations is beyond the scope of this article, but suffice it to say that these regulations are focused on industry relationships with healthcare professionals and healthcare organizations.³ Of primary concern is providing items of value (compensation, gifts, hospitality, etc.) to the healthcare practitioners and organizations, and the ability of those items of value to influence medical decision-making and prescribing behavior.^{4,5} In particular,

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Human Services.¹ The OIG report emphasized that payments for research services should be FMV for legitimate, reasonable, and necessary services. The challenge is that the OIG report did not specifically define the term or parameters around which FMV should be determined; hence, it is a primary source of confusion (see Figure 1 for excerpts from the OIG report that put the concept into additional perspective). Although most people would agree that an “OIG Reference Guide to Costing Trials—A Regulatory Auditor’s Perspective” would be a great resource to provide clearer direction, such a book does not exist; thus, there are many interpretations of what constitutes FMV for trials and how to soundly approach the issue.

Without a universally accepted regulatory definition of FMV, we turn to other sources to provide insight. The Internal Revenue Service and *Merriam Webster Dictionary* both have specific, yet different, definitions. One industry source defines FMV as a “legal term

spective, FMV is really shorthand for legitimacy; payment to physicians and investigators should be based on a legitimate business relationship that provides identifiable value to the com-

Figure 1 Excerpts from the OIG Compliance Program Guidance for Pharmaceutical Medicine¹

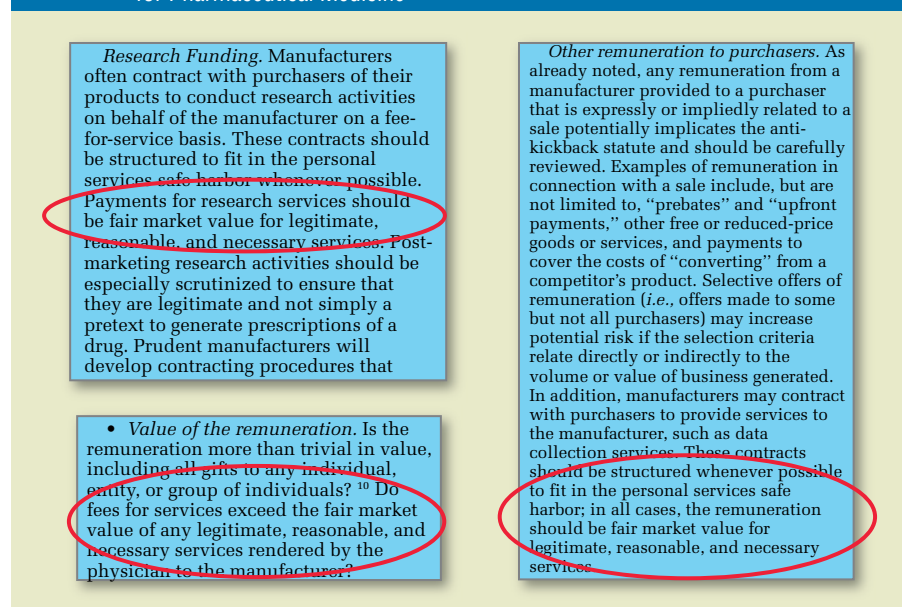
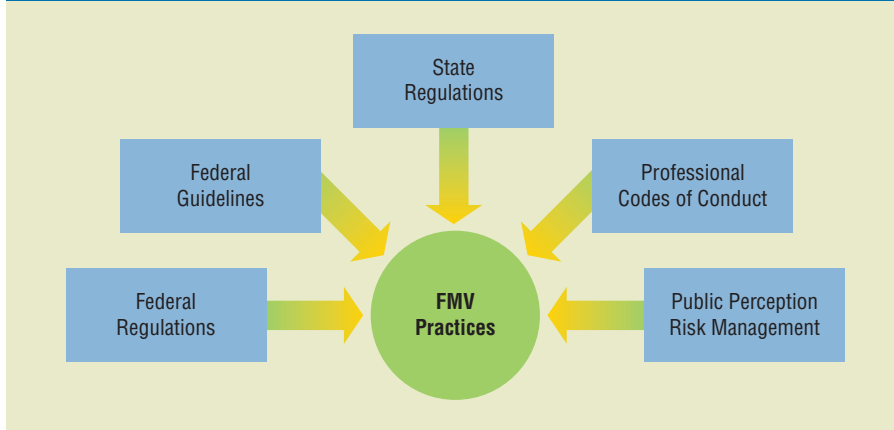


Figure 2 Factors Affecting Fair Market Value Practices



prosecutors and the OIG are becoming increasingly frustrated with companies that violate (sometimes repeatedly) the anti-kickback law, engage in sham consulting agreements with doctors, pay doctors for “seeding” studies, or entice doctors by using speaking fees.² As previously noted, the rules, regulations, and codes of conduct influencing FMV are not unique to the U.S. For example, the Eucomed Code of Ethical Business Practice stipulates that medical technology companies will compensate healthcare practitioners for legitimate consulting services, and that such compensation reflect FMV and be outlined in a written document.⁶

Why is FMV of Importance and Concern to the Pharmaceutical Industry?

Relationships with healthcare professionals and healthcare organizations are under significant scrutiny by regulators at both the federal and state levels. The trend is clear: Enforcement activity will focus increasingly on holding individuals responsible for the legitimacy of relationships between pharmaceutical companies and the physician-consultants they engage.² The bottom line is that sponsors face criminal and financial penalties if they fail to comply with the FMV guidelines and regulations.

One high-profile case tied to FMV occurred in May 2008, when Biovail

pleaded guilty to conspiracy and Anti-Kickback Statute charges, and agreed to pay a criminal fine of more than \$24 million for allegedly conducting a sham study involving Cardizem L.A. The study paid physicians up to \$1,000 per subject enrolled, and involved prescribing Cardizem L.A. for enrollees. The prescribing physicians conducted three regularly scheduled visits for each enrolled patient, which involved no additional work for the physicians, and completed short multiple-choice questionnaires. The pay-

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ments exceeded the reasonable FMV of the physicians’ time necessary to enroll the patients and complete the questionnaires.⁷ As a result of such activity as seen in this case, regulators are asking for FMV analyses for all areas of pharmaceutical companies—from medical affairs to sales and marketing to clinical research activities.

The goal and intent of FMV compensation is to reduce the apparent conflict of interest in paying doctors for services they provide to pharmaceutical companies. To comply with both the letter and spirit of the regu-

lations and guidelines, sponsors are working on ways to:

- justify the appropriateness of the payment level based on level of effort and intensity of the activities;
- determine what factors were considered in compensating for the service; and
- evaluate how those factors were validated.

How is FMV Determined?

As a practical matter, there is no clear guidance on determining FMV from the OIG; it advises only that the method must be “reasonable.”¹ Pharmaceutical companies are required to comply with the fair market standard, but the government sets forth very limited guidance in terms of how FMV should be determined.⁸ Therefore, it is really left up to industry to determine the extent of documentation that is appropriate (both in terms of justifying internal practices for how a firm establishes FMV thresholds as well as what it expects from sites).

Since there is no government-approved standard to determine FMV,

firms rely on historical data that allow them to benchmark their payments against industry-wide practices. Two often-used benchmark databases, Medidata Grants Manager^{®9} and TTC GrantPlan[®]/TTC Standard of Care^{™10}, cover the key components of investigator budgets, such as individual procedures, overhead rates, and other direct costs, but have their limitations. A recent survey by TTC and the University of the Sciences in Philadelphia found that standard-of-care costs is another important factor influencing the development of clinical trial budgets.¹¹ The results of the survey concluded that

most pharmaceutical companies are exploring ways to avoid unnecessary and potentially troublesome clinical grant payments to research investigators that should be covered by third-party payers. Although a discussion of Medicare billing compliance and standard-of-care reimbursement is beyond the scope of this article, standard-of-care pricing and payment further compound the complexity of the FMV issue.

The benchmark tools focus on “best practice pricing” vs. FMV, and there is a difference between the two. Best practice pricing starts at the 50th percentile level derived from the benchmark database. FMV depends on recent and “local knowledge” factors that may not be reflected in the benchmark database, such as the trial’s desirability to sites, patient availability for the indication, complexity of the protocol, and other factors. As a result, FMV ranges may be defined somewhat subjectively by sponsors, and the ranges vary by site type and region, although most roll up the costs into one average budget.¹²

Furthermore, benchmark databases tend to focus more on procedure costs, but it is often the personnel costs that really drive the budget disparities. The lack of a well-documented “time-and-motion study” to substantiate the “true cost” of conducting clinical trials perpetuates the imbalance between establishing budgets based on procedure costs without accounting for all of the associated support costs. “Consider the fees for performing an EKG,” notes Christine Pierre, president of RxTrials, based in Ellicott City, Md. “Many sponsors view an EKG as a standalone event, but don’t factor in the support that goes into reading and interpreting the EKG, obtaining certified copies, obtaining principal investigator signatures, faxing in the results, responding to queries, and the like. So the FMV price is based on the procedure, and not on all of the associated support time, which is a primary source of the disconnect in how sponsors and sites view and determine what is FMV.”

Nonperforming sites included in the cost benchmark databases may further skew the data.¹¹ This complication requires that sponsors parse out the true costs by performing/experienced sites vs. nonperforming sites, which is a time-consuming task. Another challenge involves trying to “compare apples to oranges” in terms of the costs for performing clinical trials at different types of research sites. For example, over the last decade or more, research has shifted from academic medical centers and hospitals to smaller professional research centers, private practices, and other types of sites, all of which have vastly different cost structures compared to the larger centers. The benchmark data

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are based on fees paid to sites over the last 10 to 15 years, which again may not reflect the costs of research based on the type of institution. In other words, the benchmark tools do not differentiate payments based on type of site. Finally, some sites may overinflate the “true cost” as a means of supplementing their income (beyond clinical practice), which further compounds the issue.¹²

All this goes to show that currently there are no well-defined or established ways to determine FMV. Regardless of a sponsor’s or site’s approach and methodology, it needs to follow some basic steps to ensure its approach is legitimate and justifiable.

What Should Sponsors Consider to Ensure Their Compliance?

Today’s environment demands consistency, transparency, and defensible methods. For example, pharmaceutical sponsors must:

- show that all sites are being fairly and consistently com-

pensated for the same level of service.

- publicly disclose the total amounts paid to individual physicians for any type of work.
- be able to defend how they determined their fee structure.

In developing FMV fee ranges, companies should not rely solely on internal historical fee data. Some industry experts advocate that sponsors should use independent external data (e.g., compensation data from different sources) and consider analogous services for comparison purposes when determining FMV fee ranges (e.g., expert witness fees or other comparable professional fees).²

With these general principles in mind, what other measures can sponsors take to ensure they are in compliance with the FMV guidelines, while also moving the projects forward and preserving their relationships with the sites? We suggest the following:

- Standardization—Auditors like documentation and standardized, repeatable processes. Sponsors should have an established methodology for budget development, along with a review process for costing studies. Limiting the number of individuals developing the budgets is one way to promote consistency. The review process could include any combination of peer reviews, third-party reviews, and consultation, as well as utilization of internal and third-party historical cost databases (with the above caveats noted regarding the limitations of these databases).
- Governance and control procedures—Sponsors should be able to demonstrate, via their stan-

dard operating procedures, that they were diligent in utilizing appropriate sources to develop the budget, and that they have a process to manage any exceptions that exceed their outlined budget parameters.

- **Documentation**—In situations where investigative sites request increases to the budget, sponsors should request documentation and justification for the proposed changes. This documentation should be filed and available for reference as evidence to support any changes to which the sponsor agrees. As a last resort, sponsors must be willing to part ways with a site if agreement cannot be reached, because no amount of documentation will defend a decision to pay 50% more for patient X at one site versus patient Y at another site when the sites are performing the same services for a given trial.
- **Site relationship management**—Preserving the relationship with investigative sites is of paramount importance for the long-term. Although the goal is to create a business relationship that is agreeable to both parties, the process of negotiating budgets within the FMV constraints can be frustrating and contentious. Many sites do not fully understand or appreciate the complexities associated with FMV, or the ramifications to sponsors if they do not comply with FMV requirements. Sponsors should help sites understand these requirements and, in turn, request that sites help support the sponsor's ability to comply by providing appropriate justification and documentation of their costs. Once agreement is reached, sponsors should ensure that they have reasonable payment terms and timely payment schedules, as cash flow is critical to the viability of many investigator sites and

is a way to promote good will in the relationship with sites that may be constrained to operate within the trial budget.

As is the case with many aspects of managing clinical research, there is still plenty of room for improvement in the area of FMV—especially in the larger institutional (academic medical center) sector, where sponsors remain challenged and uneasy about making decisions on how to account for the inherent fees that are associated with doing business with these centers. The

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latest Physician Payment Sunshine Act and other regulations with respect to healthcare practitioner spending will continue to evolve over time, as industry works with regulatory bodies to agree on the most appropriate principles and codes of conduct. In the meantime, sponsors should be prudent in their actions and establish standards and controls to demonstrate their commitment to the spirit of the guidelines and regulations.

How Can Investigative Sites Support the Budget Negotiation Process in Light of FMV Guidelines?

For industry sponsors to fulfill their obligations to demonstrate consistent, transparent, and defensible methods, they need the following from sites to substantiate the investigator grants:

- justification and documentation of the work effort involved in performing clinical research activities;
- true cost of services; and
- assurance that the payment process to the investigators is transparent.

Christine Pierre and Dr. Bucko both reinforce the importance of sites understanding their true cost of conducting clinical trials, and being able to clearly explain their cost structures to sponsors. “Fundamentally, sites lack good justification of the man hours or personnel time involved in clinical trials,” notes Pierre. Dr. Bucko adds, “The work effort involved by investigators, research coordinators, and other clinic personnel differs by phase and complexity of the trial, both of which have significant bearing on the fair market value for specific trial activities.”

Documenting the work effort involved and tracking the time for performing certain activities is a tedious and time-consuming, but valuable, exercise. Two recent efforts showcase the challenges involved in estimating work effort and variations in time allocations across different sites^{13,14}; nonetheless, they provide a good framework upon which future “time and motion” studies can be performed. Such documentation and justification of the true cost of conducting trials should go a long way to help sites more accurately estimate the time and resources required to conduct a trial, and enable sponsors to adequately compensate sites for these legitimate costs.

Summary and Conclusions

FMV is a complex issue that affects both investigative sites and clinical research sponsors. Like many other aspects of clinical research, FMV guidelines are somewhat vague and open to interpretation. Although it is unlikely that we will ever achieve clarity on specific definitions and universal agreement on what constitutes FMV, with time, experience, and continued discussions on the topic, some of the fog should

clear. Also, as with good clinical practices, an evidence-based approach with good documentation of the methods used to determine FMV is the best way to ensure compliance. From a practical standpoint, the more that investigative site managers can provide justification of their costs and work effort involved, the more they will help sponsors fulfill their FMV obligations, as well as facilitate the budget negotiation process.

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