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When Can a Study Sponsor Pay Different Prices to Different Sites and Not Violate Fair-Market-Value Principles?

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"Fair market value" (FMV) can be defined as "the price in an arm's length transaction between a willing seller and a willing buyer." When, in a competitive market (i.e., with no collusion between sellers or between buyers), like sellers are providing like products to like buyers at the same price, that price can be said to be the fair market value.

As corollaries, if the sellers, buyers or products are *not alike*, FMV principles do not require prices to be alike, and might require them to be different. For example, there is no FMV requirement to sell tomatoes at the same price in Los Angeles, California and Nome, Alaska. Going further, it would be a violation of FMV principles to sell a new Maserati for the same price as an old Kia sedan. These same principles apply to clinical research services.

A study sponsor can violate FMV principles in the following ways:

- Paying all sites too much can cause financial difficulties for the sponsor and beg the question as to whether the high payments are an illegal, general inducement to prescribe the sponsor's drugs or medical devices.
- Paying all sites too little will likely cause problems for the study but will not create any governmental issues.
- Paying all sites the same amount, regardless of their performance, will also likely cause problems for the study but will probably not lead to governmental penalties.
- Paying most sites the same amount except for a few that get significantly more — without legally acceptable justification — will expose the sponsor to the possibility of governmental penalties.
- Paying sites significantly different amounts without legally acceptable justification will expose the sponsor to the possibility of governmental penalties.
- Paying more to sites that prescribe a lot of the sponsor's drugs that are covered by Medicare is just asking for trouble.

Respecting FMV principles helps study sponsors keep sites happy and avoid regulatory compliance problems. However, misapplying FMV principles drives away good sites and overpays bad ones. As an analogy, if an NBA basketball team tried to pay the same salary to every player, it would end up with the worst team in the league. The same dynamic applies to clinical research.

A study sponsor is probably not violating FMV principles if the price it pays *comparable* sites varies by less than, say, 15%. Paying any site more than 15% of the average price must be defensible, based on the site delivering extra value to the sponsor in one or more of the following ways:

- The site is available when other sites are not available (e.g., immediately).
- The site can enroll or retain more study subjects than other sites.
- The site can enroll subjects who help the sponsor meet the study's diversity or other statistical requirements.
- The quality of the site's work is better than that of other sites.
- The site can complete the study more quickly than other sites.

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- The site can start up more quickly than other sites (e.g., in a rescue situation).
- The site has a reputation for reliability, thus reducing the sponsor's risk.
- The site is in a location with high prices for clinical research services and the sponsor needs a site in that location.
- The sponsor's costs for working with the site are lower (e.g., because it is conveniently located).
- The site is easier to work with than other sites, saving time and energy for the sponsor's study team.
- The site's services are in high demand.
- The reputation of the site or the site's investigator will give study publications more credibility.
- The site can help meet the sponsor's governmental requirements (e.g., for marketing approval).
- The site has any other special features that make it more attractive as a study site (specifically, not as a prescriber) to the sponsor than other sites.

The above discussion applies to bottom-line pricing, not the pricing of specific line items in the study budget. However, a high price for a specific line item might raise issues if, for example, payment for those items will be reimbursed by Medicare or go to a facility owned by the investigator.

Conclusion

Healthy market dynamics ensure that prices are basically fair to both buyers and sellers. However, because pricing in the clinical research services market can be wrongfully influenced by the much larger heathcare market, the U.S. government employs FMV principles to deal with instances when mispricing costs the government money, either directly or indirectly.

Unfortunately, study sponsors often apply FMV principles incorrectly, causing unnecessary problems for their studies and the health of the clinical research enterprise.

Clinical research sites that want to charge premium pricing must justify that pricing to sponsors based on the above rationales and hope the sponsors understand the correct application of FMV principles.

Disclaimer

This article is for general information purposes and is not legal advice. Consult with a qualified attorney concerning any legal questions you might have.

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