Journal of Clinical Research Best Practices

Vol. 13, No. 12, December 2017 "Happy Trials to You"

What is Fair Market Value?

By Norman M. Goldfarb

"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 fair market value.

However, in a market like clinical research in which the sellers (clinical research sites), the buyers (study sponsors and CROs), and the products (study conduct) are highly variable, FMV is a more complicated concept.

What Do We Mean by "Arm's Length" and "Willing"?

The principle of "arm's length" means the parties to a transaction can act independently, i.e., neither is subject to coercion or undue influence from the other party. The principle of "willingness" means each party in a transaction can act in his or her best interests. In combination, these two overlapping principles mean each party to a transaction can act independently in their own interest, i.e., they have "autonomy."

On the other hand, the principles of beneficence and justice, while they might be good business practice, are not required in the market for clinical research services, except as required by the Stark, False Claims, and anti-kickback laws, which employ FMV principles.

Coercion, undue influence, and "tied" buying or selling can violate the principles of autonomy and willingness, and thus lead to FMV violations.

In a tied transaction, the sale and purchase of one product influences the sale and purchase of another product. For example, a study sponsor cannot award a lucrative clinical study to a physician on the condition that he or she will prescribe more of the company's other products.

In the absence of the principle of beneficence, buyers and sellers are free to exploit the other party and take advantage of their ignorance, stupidity and desperation, within the bounds of the law. For example, a clinical research site is free to discount its services below cost. If, for whatever reason, it can charge more than other sites for conducting a study, it is free to do so. Similarly, a study sponsor is not required to pay a higher price than is neecssary to recruit the sites it needs for a study. Of course, the sponsor has to accept the risk that those sites might not deliver on their commitments.

What Isn't FMV?

FMV is not necessarily…

- **Based on cost.** Costs certainly influence price, since most sellers want to price their product at or above their cost. However, it is the value *to the seller* that matters. For example, if a clinical research site's rent goes up, that does not increase value for the seller.
- **The same as clinical care pricing.** Here is an example where costs influence price. For example, if a test performed for a study requires more paperwork than a test performed for clinical care, one would expect the price to be higher in a competitive market.

- **Based on Medicare or insurance reimbursements.** Medicare reimbursement rates are set by the U.S. government, not in a competitive market (although, if healthcare providers stop seeing Medicare patients, the government would have to adjust pricing). Insurance reimbursement pricing is low when insurers can use their volume purchasing power, and higher in markets that healthcare providers control.
- **The same for all sites in a study.** Sites are often not *like* sellers providing *like* products (as discussed below).
- **The same in different hospital departments.** For whatever reason, many hospitals price clinical care services differently in different departments. The price for these services for clinical research can vary accordingly.
- **The same in the same hospital department.** For example, two physicians in a hospital department might charge different prices for the same clinical care procedure. The price for these services for clinical research can vary accordingly.
- **The same price everyone is charging.** Consistent pricing in a market suggests, but does not prove, the presence of FMV pricing. For example, the price of a medical procedure in two very similar, neighboring towns can vary substantially.
- **"Fair" in the buyer's or seller's mind.** FMV does not mean that every seller has the right to make a reasonable profit, or that every buyer has the right to buy a product at a price it can afford. Any parent of two or more children knows that fairness can be in the eye of the beholder.
- **Identical for like transactions.** Consistent pricing does not mean every like transaction has to be at exactly the same price. As a matter of practicality, the government allows some flexibility. It has not published guidance on how much flexibility is allowed under the law, but some lawyers guess it might be 10% to 15%.

What Determines Value?

In a perfect commodity market, all products are identical, so buyers do not care who provides them, and all sales are at the same FMV price. However, the "products" in the clinical research services market are not identical and can be sold at different prices without violating the FMV principle.

A clinical research site might be able to charge premium prices for the following reasons:

- **Quality.** It might perform a procedure especially accurately or safely.
- **Availability.** It might have the capacity to take on a study, while other sites are busy with other studies.
- **Volume.** It might be able to enroll a high number of patients, or be willing to conduct the study with a low number of patients.
- **Delivery.** It might be able to enroll patients exceptionally quickly.
- **Location.** It might be expensive but still be in the most affordable in a particular city. Or, it might be located conveniently close to the sponsor.
- **Reliability.** It might have a proven record of consistent performance, thereby reducing the sponsor's risk.
- **Reputation.** It might have such a strong reputation that sponsors clamor to place studies there.
- **Risk.** It might have an unblemished record of "no findings" in regulatory inspections.
- **Indirect costs.** It might have a characteristic that reduces the sponsor's other costs, e.g., by minimizing site monitor travel time and cost.
- **The point in time.** It might be able to conduct a study over the holidays.

- **Special circumstances.** It might be willing and able to serve as a rescue site.
- **Special features.** It might have an advanced piece of equipment.

A site that lacks these features will probably not be able to charge premium prices.

Different sites can have different pricing strategies. For example, one site might offer low introductory pricing to sponsors that promise future business, while another site might offer low prices to repeat customers.

The first strategy can be justified under FMV if the new customer incurs higher costs and/or takes a greater risk with a new site. The second strategy can be justified under FMV if the established customer incurs lower costs and/or takes a lesser risk.

The first site is not required under FMV to offer introductory pricing to all new customers because the discount is, essentially, a marketing cost that the site expects to amortize over future studies from that sponsor, from which it will earn profits and incur lower marketing costs.

Value Matters

One study (A) might require a single blood pressure measurement of a sitting patient, while another study (B) might require two blood pressure readings, two minutes apart, of a prone patient. While both procedures record the patient's blood pressure, the second procedure is more time-consuming and produces a measurement that, presumably, has more value to the sponsor.

All other things being equal, the principle of FMV is violated when…

- **A site charges different prices to different sponsors for the same service.** For example, a site might want to charge two different sponsors different prices for the same measurement A.
- **A sponsor pays different prices to different sites for the same service.** For example, a sponsor might want to pay two different sites different prices for the same measurement A.
- **A site charges the same price to different sponsors for different services.** For example, a site might want to charge one sponsor $20 for a measurement A and a different sponsor the same $20 for measurement B.
- **A sponsor pays the same price to different sites for the different services.** For example, a sponsor might want to pay $20 to one site for measurement A and the same $20 to a different site for the measurement B.

Who Determines FMV?

The market determines FMV. The best indicator of FMV is price, i.e., "what the market will bear." In a perfect commodity market, this price is a single number. For example, every ounce of gold (in a specific location) is "fungible," i.e., interchangeable, so everyone who wants to buy an ounce of gold at a specific point in time should pay exactly the same price. However, as explained above, because clinical research services are not fungible commodities, they vary dramatically.

In addition, a perfect market requires timely and accurate information on the product and its related transactions. The market for gold is relatively perfect, although some buyers and sellers can better estimate trends in demand and/or supply, and thus future prices.

Sponsors have only imperfect information about the clinical research services that a site can offer at a specific point in time. Sites have even less information about the services other sites provide. Commercial databases are available with very detailed information on the prices that sponsors have paid to sites, but the high cost of these databases has largely limited their use to large sponsors and CROs. Other sponsors, CROs and sites can look at their own pricing histories.

FMV can be considered the average price paid for a specific clinical service, adjusted for the factors listed above. Because information about the services, their prices, and current trends in supply and demand is limited, market participants can only estimate FMV. They can approximate FMV by raising or lowering their prices until they find enough sellers or buyers to meet their needs.

Sponsors could determine FMV more accurately by conducting an explicit auction among the sites interested in conducting a specific study, with adjustments for quality, timeliness, etc. Many sponsors, in essence, employ a crude auction technique when they simultaneously negotiate prices with multiple sites.

Final Points

Value to the buyer, not cost, determines FMV, although cost is a contributing factor. The market sets FMV but is limited by the wide variety in clinical research services and the market participants' imperfect information.

Just as a sponsor cannot pay two sites different prices for equivalent services, it cannot pay two sites the same price for different services that provide different value. In words, FMV *requires* sponsors to pay higher prices than average to sites that enroll patients and deliver quality data in a timely manner, provided the clinical research market values performance, as it should.

Sponsors must apply their pricing policies consistently. For example, to ensure geographical diversity, a sponsor might decide to pay sites in expensive regions more than sites in inexpensive regions. If so, it must adjust pricing for all sites in those regions consistently (and not just to the sites who raise the question).

Each site should establish a standard price list ("rate card") for its services. Rate cards can consider quality, availability and the other factors listed above. Sites do not need to share all this information with sponsors.

Sites must apply their pricing policies consistently. For example, if they want to charge a higher price for a specific study, they have to be able to explain to the government how that price is consistent with their rate card. If a site's rate card allows raising prices on vaccine studies over the holidays, it must apply the higher price to all sponsors, without discrimination.

In some circumstances, exceptions can be made. For example, a sponsor might want to help a site get through a rough patch so it can return to providing good service. However, an exception that occurs multiple times should become a policy.

If the government comes to call, sponsors and sites must be able to provide written documentation explaining their pricing rationale, how it was applied to each clinical trial budget, and the reason for any exceptions. Every pricing action must be *defensible*.

Markets do not run on sympathy. If you are a sponsor and cannot afford to pay the market price, or you are a site and cannot afford to charge the market price, too bad.

For too long, many sponsors have incorrectly interpreted FMV to mean "pay the same price to all sites." This policy works to the disadvantage of sites that provide superior services, to the disadvantage of sponsors that would benefit from those superior services, and to the disadvantage of patients who, as result, have to wait longer for treatment.

Other Reading

Norman M. Goldfarb, “FMV and the Market Failure in Clinical Research,” Journal of Clinical Research Best Practices, July 2016

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.

