Fair Market Value for Clinical Trials: Risk Mitigation

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Why Do We Care About FMV?

  - OIG has identified three major potential risk areas for pharmaceutical manufacturers:
    - (1) integrity of data used by state and federal governments to establish payment;
    - (2) kickbacks and other illegal remuneration; and
    - (3) compliance with laws regulating drug samples.
  - Research Funding Principle:
    - Payments for research services should be fair market value for legitimate, reasonable, and necessary services.
How is FMV Defined?

In the non-healthcare business community, Fair Market Value is defined as “the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.” – International Glossary of Business Valuation Terms
“Fair market value means the value in arm’s-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.”
FMV according to OIG & CMS

• OIG Compliance Guidance for Individual and Small Group Practices (October, 2000)
  – “The OIG’s definition of FMV excludes any value attributable to the referrals of Federal program business or the ability to influence the flow of business. Adhering to the rule of keeping business arrangements at FMV is not a guarantee of legality, but is a highly useful general rule.”

• In rulemaking, the Centers for Medicare and Medicare Services (CMS) defines market value as “the value in arm’s length transactions, consistent with the price an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party.” 60 FR 41921
Sources of FMV for Clinical Trials

• Using Medicare Pricing to Construct Clinical Trial Budget
  – Upsides:
    • Medicare pricing for clinical services is documented and publicly available
    • Legal risk for paying outside FMV for clinical services is mitigated
  – Downsides:
    • Most sites will reject Medicare pricing as being well below FMV
    • Bargaining position with a site is impacted if proposed budget is seen as unreasonably low
      – Note that Medicare creates and publishes the prices for medical services without the providers of these services having had an opportunity to negotiate the prices
Using Commercial Databases to Determine FMV (Benchmark Pricing)

• Several Databases may be consulted for a fee to ascertain a range for clinical services FMV (25\textsuperscript{th}% - 75%), e.g. Metidata Grants Manager & IMS Health GrantPlan
  – Upsides:
    • Database searches can be tailored to geography and provide ranges
    • Good faith effort to provide FMV remuneration
  – Downsides:
    • Data is often stale
    • KOLs are likely to command higher than 75\textsuperscript{th}%
Relying on Institutions Charge Master

• Institutions may rely on their internal list of items billable to insurance companies (the charge master) to determine FMV or as a tool for negotiating clinical budgets.
  – Upsides:
    • Charge masters are typically updated annually, so they are current
    • A number of institutions pay an external consultant to assist in creation of the charge master
  – Downsides:
    • Charge master lists are used to negotiate with commercial insurance companies, which tend to agree to pay a percentage of the proposed fee, so there is incentive for the charge master fees be high
Tricky Line Items

- Line items that perpetually generate protracted negotiation and can present risk to the company include:
  - Indirect Costs (IDC) or costs not tied to a specific budget line item, e.g. administrative support
  - Screen Failures
  - Start-up Costs
The Anti-Kickback Statute (42 CFR §1320a-7b(2))

- Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . .
  - (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
  - (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

- Note that willfully soliciting or receiving such remuneration carries the same risks under the AKS
Additional AKS Penalties

• The Balanced Budget Act of 1997 added a civil monetary penalty of $50,000 per act plus up to three times the amount of illegal remuneration.

• The Office of Inspector General (OIG) can also impose administrative sanctions on civil violators, including exclusion from participation in Medicare.

• In 2010, the Patient Protection and Affordable Care Act (ACA) “expanded” the AKS’ intent standard and specified that violations of the AKS may trigger liability under the False Claims Act.
The False Claims Act

• In relevant part, under the FCA, any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” or who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government.” 31 U.S.C. §§ 3729(a)(1)(A)–(B).

• By violating the FCA, defendants are liable for three times the government’s damages plus a civil penalty of $5,500–$10,000 for each false or fraudulent claim submitted to the government for reimbursement. 31 U.S.C. § 3729(a).
Example Settlement Involving FMV in Clinical Trials

In May 2008, Biovail Pharmaceuticals, Inc. pled guilty to conspiracy and AKS charges, and agreed to pay a criminal fine of $22.2M, $2.4M in FCA civil fines, and entered into a five year CIA for allegedly conducting a sham study re: Cardizem L.A. (diltiazem).

- Relevant Facts:
  - Biovail paid physician investigators up to $1,000 per subject if they enrolled 11-15 patients in the trial, which led to Rx of Cardizem.
  - Physician investigators conducted three visits for each patient enrolled in the study, each of which involved no additional work for the physician investigators, and completed brief multiple-choice questionnaires.
  - The payments exceeded the reasonable FMV of the physicians’ time necessary to enroll the patients and complete the questionnaires.
Thank you