



Fair Market Value Framework Panel – Key Considerations

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Panelists

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Disclaimer

The opinions expressed by the participants during this session are their own individual opinions and not those of the companies for which they work.

Discussion Topics

Why Fair Market Value?

HCP Compensation

Compensation to Patients and Patient Organizations

Bona Fide Services

Collaboration (Data) Arrangements

Why Fair Market Value?

- If a payment for services to (1) a customer or (2) a person or entity that is in a position to exert undue influence on patient behavior exceeds the **fair market value** of the services, the pharmaceutical company can be subject to regulatory rebukes, in addition to various penalties and fines that can be enforced through the Department of Justice (DOJ) or the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS).
 - Companies with products covered under government programs (e.g., Medicare, Medicaid) are subject to the Anti-Kickback Statute, Stark, FCPA, False Claims Act and Transparency reporting, e.g.
 - Both civil and criminal penalties can come into play
- Definition of **fair market value** as provided by the Stark regulation:
 - 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 who are not otherwise in a position to generate business for the other party, OR compensation in a service agreement as the result of bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for the other Statement of FMV compensation for **services rendered and needed**
- No Quid Pro Quo

Why Fair Market Value? (cont.)

- Compensation financially sustainable for an organization.
- Fair market value is not just for CIA compliance!
 - Updates to AdvaMed
 - Government Pricing and FMV
 - Establishing healthy relationships

- What are some of the challenges in determining appropriate compensation for healthcare professionals and other external experts include?
 - Amount of travel time compensation (TTC) as part of total honorarium
 - Alternative travel
 - Personal segments
 - Prorated RRC
 - Speaker program series, i.e., speaker travels to another part of the country and conducts multiple speaker programs over the course of several days
 - Amount to pay for more than one program in a day?
 - Travel payment between events?
 - Specialized nurses, PhDs, etc.
 - ?
 - ?

Compensation to Patients and Patient Organizations

- What are some of the challenges or considerations with determining the amount to pay patients or patient organization representatives?
- Do payments to these groups create a greater risk than payments to healthcare professionals?
- ?
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Bona Fide Services

- What are bona fide services and why do they matter? Who needs to know this information and how is it communicated to them?
- What is your process for determining whether or not a service passes the four part bona fide service fee test?
- When assessing fair market value for bona fide services, who drives the process? (business, legal, compliance, government pricing) Is the process typically performed under legal privilege?
- How long are valuations valid?
- Can FMV assessments for bona fide services be used across multiple products?

Collaboration (Data) Arrangements

- Has your company entered into any collaboration agreements with hospital systems, research organizations, PBMs, etc.?
 - Was fair market value considered?
 - How were the value of the contributions (de-identified patient data, claims data, HEOR, etc.) of each party to the collaboration determined?
- What best practices did you observe or would you recommend during the contracting phase of the collaboration agreement?
- ?
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