

# *Bona Fide* Service Fees

- **Context**
  - Impact of arrangements with Distributors/Wholesalers on Government Pricing Calculations
    - Letter to HDMA re fee-for-service arrangements
  - Medicare ASP
    - Q&A to industry
    - 2006 Physician Fee Schedule Rule
    - 2007 Physician Fee Schedule Final Rule
    - Scope of issue expanded to fees paid to PBMs and GPOs
  - Final Medicaid Rule
    - July 2007
  - Anti-Kickback Act and False Claims Act implications
- **Significant uncertainty remains about scope and requirements of these rules**

## ***Requirements* for excluding *bona fide* service fees from Medicare ASP, and Medicaid AMP and BP**

- Services must be necessary and itemized in writing
  - Actually performed by an entity on behalf of manufacturer
- Must reflect FMV
  - Are paid for by manufacturer at same rate had services been performed by other entities
- Fees not passed on in whole or in part, directly or indirectly down the chain
- If not a *bona fide* service fee, then treat as a price concession

# Risks

- Nature of the Services
  - Core versus non-core services
  - “efficient distribution of product”
  - GPO administrative fees, PBM fees
- Who do the services benefit?
- Determining Fair Market Value
- “Not Passed Through” criteria
- Commingling of *bona fide* service fees and price concessions with same or related 3<sup>rd</sup> parties

# Mitigating the Risk

- Thorough FMV analysis
- Conduct FMV analysis contemporaneously and update periodically
- Documentation
- Transparency in submissions to CMS
- Appropriate language in agreements with 3<sup>rd</sup> parties to pay such fees

# Valuation Basics

- ***Fair Market Value*** - price at which items or services would be exchanged between a willing buyer and seller, neither being under any compulsion to buy or sell and both having reasonable knowledge of the relevant facts, and without consideration of either party's position to make or influence orders or utilization, to furnish items or services to, or otherwise generate business for the other party at the time of the agreement
- ***FMV*** means value in arm's-length transactions, consistent with general market value
- ***General market value*** means 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, at the time of the service agreement

# Fair Market Value

- FMV is a range
- Alternative Methods
  - Cost Build-up Method (a form of Cost Approach)
    - Estimate should not exceed cost to obtain substitute service from third-party
    - Include a reasonable profit
  - Similar Transaction Method (a form of Market Approach)
    - Look at *comparable* transactions in the market place
    - Effective if similar transactions exist
  - Income Approach
    - Looks at present worth of future economic benefit
    - Value is dependent on the amount and timing of cash flows generated by the business, asset, or service
- Use multiple approaches when possible. Document rationale for using selected approaches