New Trends in the Use of Fair Market Value Concepts

PCF Disclosure, Transparency, and Aggregate Spend Conference
February 6, 2014

Huron Life Sciences

ROPES & GRAY

Eisai

Agenda

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Today's Speakers

Speakers

Eve Brunts
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Today's Discussion Topics

Today's Discussion Topics

Regulatory trends are causing an increasing emphasis on Fair Market Value ("FMV") by pharmaceutical manufacturers in meeting their compliance obligations for a wide range of activities. Areas recently posing challenges include:

- Healthcare Professional FMV
  - Domestic
  - International
- Clinical FMV
  - Research and Development
  - Clinical Trials
- Service FMV
  - Wholesalers
  - Specialty Pharmacies
  - Group Purchasing Organizations
- Equipment, Supplies, and Other Goods FMV
  - Goods provided in connection with other arrangements

The panel's focus will be to discuss the impact of new regulatory guidance on pharmaceutical companies' contracting processes and agreements.

Background

Before the Federal Sunshine Law

Historical Fair Market Value (FMV) Principles

- Support for payment
  - Market price
  - Compensation surveys
  - Independent third party valuation
- Transparent methodology
  - Variables in calculating FMV and method for calculation
- Consistent application
  - General values with clear basis for exception

Background

Implications of Federal Sunshine Law

- No requirements relating to payment of FMV
  - FMV requirements still derive from fraud and abuse laws
- New guidance on FMV
- New rules for identifying independent value
  - Potential conflict with fraud and abuse laws
- New need to assign value to certain products and services
  - Guidance on determining FMV
- Internal and external scrutiny of payments
  - How FMV is determined and supported?
  - Are payments consistent with FMV?

Background

Implications of Federal Sunshine Law

- General Federal Sunshine Law Guidance on FMV
  - Value = Discernible economic value on open market
    - Value reported if discernible even if no value to particular recipient
    - Value reported even if recipient did not request transfer
    - All aspects of value must be included in calculation (e.g., tax and shipping)
  - Manufacturer must make good faith effort to determine value and manufacturer accorded some flexibility
- Specific Federal Sunshine Law Guidance on FMV
  - CMS has provided guidance on specific transfers. Even with guidance, there may still be questions about applying guidance.
  - Example: CMS states that article reprints should be valued at manufacturer cost, but how is manufacturer cost determined for specific reprint if manufacturer has volume based discount so that price per reprint decreases?

Background

Implications of Federal Sunshine Law

Potential for Conflict in Identifying Independent Value

Compare Anti-Kickback Statute

"A related issue is the practice of giving away free computers. In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service being provided and that the purpose of the free computer is not to induce an act prohibited by the statute." 56 Fed. Reg. 35952, 35978 (July 29, 1991)

With Federal Sunshine Law

"Is study equipment, implantable devices, instrumentation, or other supplies provided to a covered recipient by an applicable manufacturer in connection with a FDA approved clinical trial for use solely in a research project considered a transfer of value? Yes . . ." (FAQ8264)

Domestic Healthcare Professional FMV

Background

Healthcare Professional FMV continues to be an important compliance consideration due to changing regulatory drivers, especially the Sunshine Act. Companies need strategies and tools for implementing payment structures and harmonizing processes across the organization to aid in balancing risk and business need. Important considerations in HCP FMV include:

- Does the compensation represent fair market value in an arm's length transaction for the items and services?
- Is the determination of fair market value based upon a reasonable methodology that is uniformly applied and properly documented?
- Is the compensation commensurate with the fair market value of an HCP with the skill level and experience reasonably necessary to perform the contracted services?
- Should HCP payments be bundled, or itemization into prep time, travel time, and service time necessary?
- What is the appropriate treatment of travel time?

Domestic Healthcare Professional FMV

Discussion Topics

Newer issues as a result of Federal Sunshine Law:

- Ambiguity regarding what should be reported.
- Dispute resolution process between Company and HCPs.
- Other transparency requirements – Clinical Trial Financial Disclosures and reporting significant transfers of value (TOV) of other sorts.

International Healthcare Professional FMV

Background

International Healthcare Professional FMV is becoming an ever-more important compliance consideration due to evolving guidelines. This is especially true in Western Europe and Asia where current trends are focused on increasing transparency, as evidenced by increased regulations, specific mention of FMV in guidelines, and increased FCPA fines over the last 5-10 years. Along with the considerations listed in the prior slides, International HCP FMV has additional important considerations:

- Data availability in some countries may be limited because governments do not collect and/or report information.
- Inflation in certain countries, such as hyperinflation in Venezuela, creates complexity in providing long term values.
- Physician subspecialty data is often difficult to find.
- Should countries be grouped together by region, economic status, other?
    - While it may be easier to group all African countries together; the economic characteristics of the two countries may be too disparate for an effective grouping (i.e. Sierra Leone vs. South Africa).
- Multiple factors may need to be considered for each country, including GDP, PPP, physician density, hours worked, etc.
- Health care professionals in public service versus private practice.

International Healthcare Professional FMV

Additional Discussion Topics

- How do you plan to operationalize your international HCP FMV?
  - Grouping country rates may reduce administrative complexity, but may increase risk due to a decrease in precision for certain countries.

Clinical FMV

Background

Clinical FMV projects are now in higher demand due to upcoming reporting requirements in the Federal Sunshine Law. Companies are concerned about how grant payments and clinical trial payments may be viewed by the public because unjustified or unapproved reallocation of payments may create a perception of improper influence or a pretext to generate prescriptions. Specific areas of concern include:

- Payments for services and activities have not been accounted for in more than one study budget cost category (no “double-counting” of study costs).
- All payments are assigned to a defined service and activity, mitigating the risk associated with a site subjectively reallocating funds for costs not approved.
- Valuation of items provided to clinical sites, such as items not available in public markets (pre-market drugs).

Clinical FMV

Additional Discussion Topics

- Why is Clinical FMV so challenging?
- How do you determine budgets for clinical studies?
- What FMV tools are currently being used in clinical activities? Do they align with commercial FMV rates?
- How do you deal with FMV exceptions and budget increase requests?
  - If you increase one study budget, should you increase all budgets?
  - What documentation supports modification of study budget for a clinical site?
- How do you manage FMV via third parties (CROs and etc.)?

Clinical FMV

Additional Discussion Topics

- Do you plan to allocate and report payments to the optional Federal Sunshine Law categories?
- Do you anticipate any changes after Open Payments is publicly available?
- How do you establish FMV for patient compensation?
- Do you allow office staff to attend Investigator meetings?
- How does the UK Anti-Bribery Act and local codes affect clinical activities and R&D engagements?

Service FMV

Background

There are many laws / regulations that drive the need to determine fair market value for services provided by third party vendors, such as:

- Government Pricing – To properly treat Fee-For-Service payments in the calculation of government pricing.
- Anti-Kickback / Stark – To provide the correct amount of payments to, or receive from, healthcare providers and research entities.
- HIPAA Privacy Rule – To assess the reasonable amount payable to covered entities (e.g., pharmacies) for marketing and communications to patients.
- Federal Sunshine Law / Open Payments – To determine a direct or indirect Transfer of Value, that has "discernible economic value on the open market," in properly reporting non-financial payments to physicians.

The trend is clear – more emphasis on FMV to better monitor costs and compliance.

Examples of Services Obtained from the Distribution Channel

Below is a partial list of services and data that Huron has experience in valuing.

GPOs, MCOs, and PBMs	Specialty Pharmacy	Wholesalers and Distributors
• Administrative fees paid to GPOs including the services listed herein • Audit wholesaler data • Billing resolution, chargeback, and rebate issues • Contract modeling for member on manufacturer's behalf • Customer notification of changes in contract prices or terms • Data reporting – sales and market share • Exhibits and meeting attendance • Focus groups/advisory boards • Maintenance of customer lists • Market research • Program oversight and contract consulting • Promotional activities such as email blasts and webcasts • Provision of contract modeling tools • Speaker programs • Sponsorships	• Adverse event reporting • Call center • Complex benefits investigation • Compliance and persistency programs including the services listed herein • Coordination with call center hub • Custom scripted calls to patients • Data regarding inventory levels, transactions, and patient status (e.g., "852/867 Data, weekly shipped/reimbursed data") • Express shipping • High-risk patient assessments • Inventory management • Product replacement services • Sending promotional or educational materials • Single site redistribution services	• Chargeback administration • Customer service levels • Data regarding inventory levels, transactions, and patient status (e.g., "852/867 Data") • Inventory management • Third-party contract administration

Service FMV

Additional Discussion Topics

- Have your firms implemented a fair market value compliance program?
  - What does it look like?
  - What are primary processes that were put in place?
  - Does the program provide FMV for all types of services?

- Please discuss some challenges with vendors in implementing the FMV compliance program.

- Does the HIPAA Privacy Rule involve a different standard of value from BFSF (Bona Fide Service Fees) or Anti-Kickback? What is your standard for Open Payments?

General Considerations

- Privilege or no privilege on projects to determine FMV
  - When and when not to use?
  - Small company vs. large company?
- What should companies look for in their FMV advisers?
- What documentation should be maintained on FMV analysis, rates, and exceptions?

General Challenges

- Consistency across company or companies
  - Different divisions
  - Clinical versus commercial
  - Different companies subject to consolidated reporting
- Global payment *versus* hourly rate
- Service *versus* service provider
- Nature of service *versus* lost opportunity costs
- Benefit to covered recipient *or* collaboration
- Different industry approaches mean “apples to oranges” comparisons
  - Services/expenses covered by payment

Specific Valuation Issues

- Determining existence of independent value and FMV
  - Third party products and services
  - Periodic use of product (device)
  - Unapproved/uncleared investigational product
  - Expired product/non-sterile product
  - Continuing medical education credit
  - Education/training (including product specific and more general disease state/treatment options)
  - Medical writing support
  - Educational materials (including materials produced in-house)
  - Clinical trial services (provided by site and provided to site – e.g., central labs)
  - Products never sold on market (so no discernible value, including approved/cleared products)

Question and Answer

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About the Speakers

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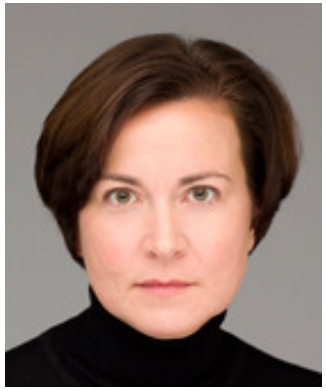

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Eve Brunts is a partner in the Health Care Practice at Ropes & Gray LLP. Eve has extensive experience in advising pharmaceutical and medical device manufacturers on a wide range of regulatory and compliance issues of concern to the industries, including compliance with federal and state marketing conduct and disclosure laws. Eve has assisted both pharmaceutical and medical device manufacturers to: (1) assess the applicability of disclosure laws; (2) interpret ambiguities in the laws; (3) undertake internal assessments to identify reportable transactions and evaluate tracking capabilities; (3) develop policies and procedures to track, characterize and report transactions, including fair market value fee schedules; (4) implement training programs; (5) benchmark interpretations and practices against industry peers; and (6) respond to audits and identified non-compliance under state laws.

About the Speakers

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Janice Kam has been with Eisai Inc. since October 2012. At Eisai, Janice's primary focus is Customers & Payors, which encompasses providing legal counsel on a variety of issues relating to managed markets, trade, reimbursement, health economics and government affairs. Before joining Eisai, Janice spent several years at Medco Health Solutions, Inc., supporting pharmaceutical strategies and solutions, and prior to Medco, Janice was at Pfizer Inc. providing support to managed markets.

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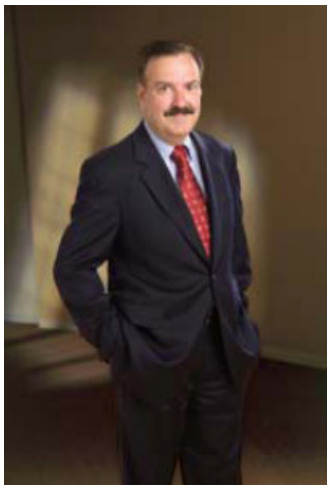

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Mark DeWyngaert has provided operational, clinical, managerial, consulting, and litigation services to various segments of the health care industry. Mark trained as a molecular biologist and has been actively involved in both research and business development roles for the past 25 years. He specializes in assisting pharmaceutical manufacturers, biotechnology, and medical device companies with identifying and mitigating regulatory risks and valuing intellectual property.

Thank you for your participation.