

# The Implementation of Fair Market Value

*What can we learn from recent enforcement actions?*

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# Today's Discussion Agenda

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- ❑ Background on fair market value
- ❑ Where fair market value can impact our business
- ❑ Discussion of recent investigations
- ❑ Developing a fair market value process
- ❑ Determining fair market value for programs and services
- ❑ Implementation considerations

# Regulatory Background

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- ❑ Relationships with healthcare professionals and healthcare organizations are under significant scrutiny by regulators at both the Federal and State levels.
- ❑ Key concern is providing items of value (compensation, gifts, hospitality, etc.) and the ability of those items of value to influence medical decision making.
- ❑ Several States have passed laws requiring manufacturers to track what is being provided to healthcare professionals and MN prohibits gifts to healthcare professionals greater than \$50 in a year.
- ❑ There is Federal legislation pending to require pharmaceutical manufacturers to track and disclose spending on healthcare professionals as part of a national registry.
- ❑ There were 5 Deferred Prosecution Agreements in 2007 with Medical Device Companies focused almost entirely on their relationships with healthcare professionals.

# Focus of the Recent Device Matters

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## ❑ Demonstrating the “need” for the service

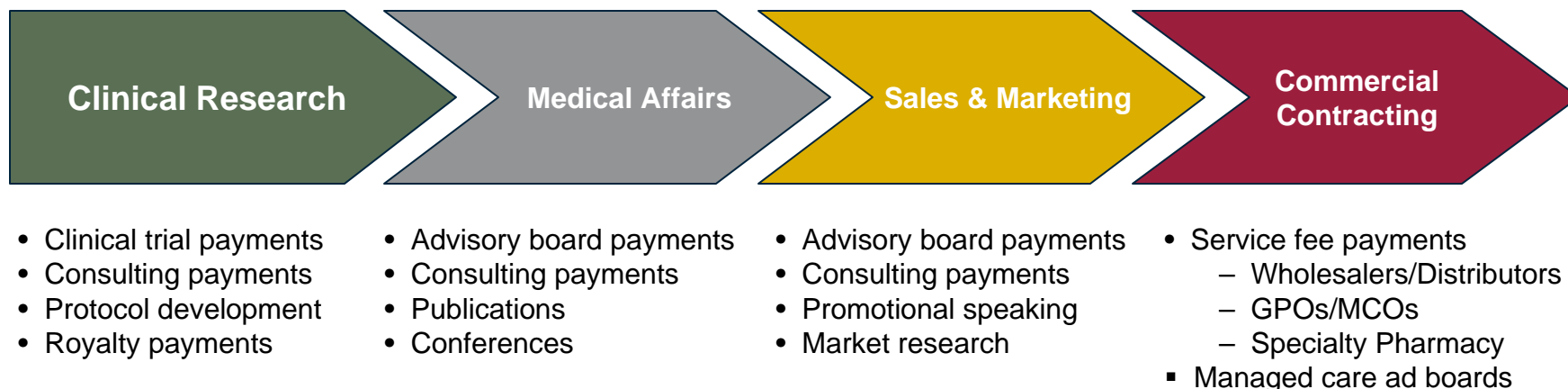
- How did the company determine the overall number of service activities that were needed?
- How was the determination made of how many HCPs are needed to provide the service?
- How was the determination of the individual HCP made to provide the service?

## ❑ Justifying the appropriateness of the payment level

- What was the HCP compensated to provide the service?
- What factors were considered in compensating for the service?
- How were those factors validated?

# Where can FMV Impact our Business

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- ❑ The FMV “touch-points” are throughout the company
- ❑ Compensation levels for a similar level of effort should be harmonized across the functional areas of a company
- ❑ Regulators are asking for fair market value analysis for all areas of the company

# Demonstrating “Need” is Critical

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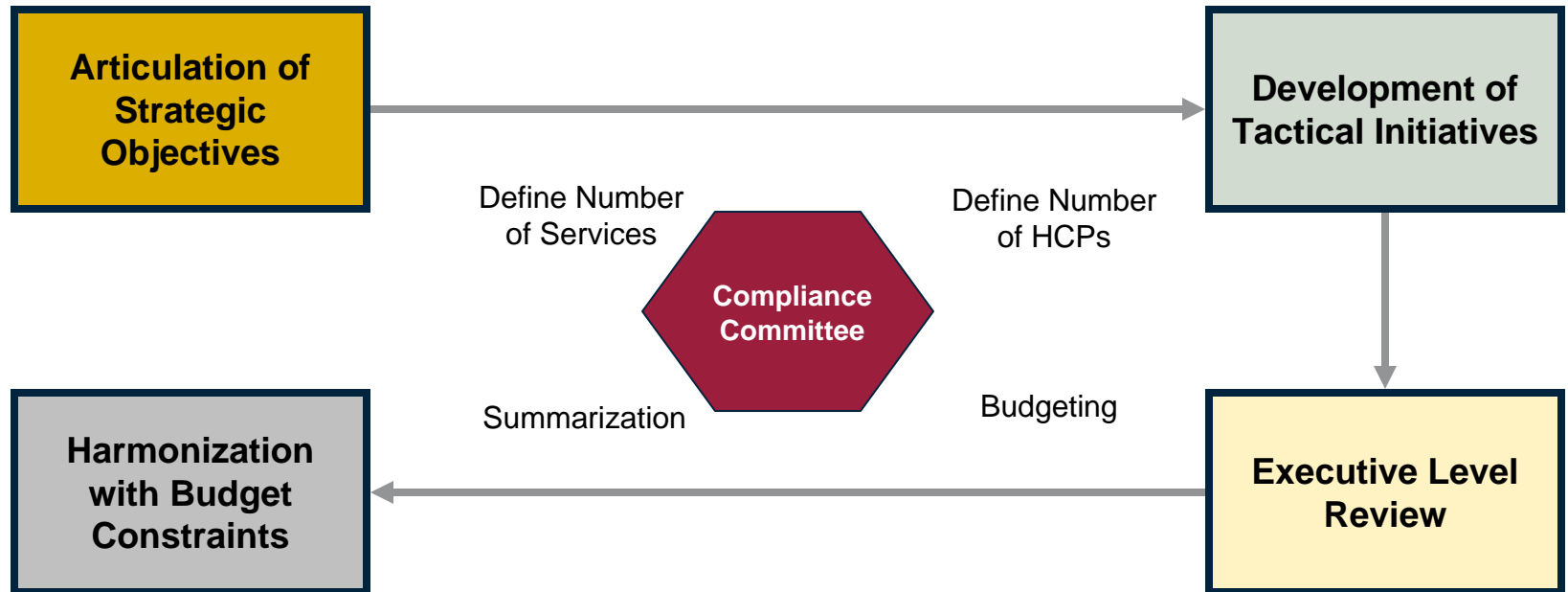
- ❑ How did the company determine the overall number of service activities that were needed?
  - What was the rationale for the number of consultant meetings, advisory boards, and other activities involving HCPs
  - Benchmarking historical levels of activities may be one data point; however, it is generally not sufficient on a “stand alone” basis
  - Could a “bottom-up” forecast of services be developed of each service activity by brand/product group and functional area?
- ❑ How was the determination made of how many HCPs are needed to provide the service?
  - What was the basis for the total number of service activities and the frequency of each individual activity
  - Promotional meetings, advisory boards, consultant services, etc.
- ❑ How was the determination of the individual HCP made to provide the service?

# Managing “Need” Against Budget

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- ❑ Highly sensitive area of discussion for the Government
- ❑ Services should be driven by business need and not availability of budget funds
- ❑ Budget parameters should be a data point in the decision making process, but not the primary data point
- ❑ The services should be identified by a “bottom-up” estimate of need by functional area and strategic objective
- ❑ The “bottom-up” need should then be managed against any budget parameters

# The Structure Used in the DPA Environment



- ❑ Cross-Functional compliance committee
- ❑ Articulation of strategic objectives
- ❑ Development of tactics
- ❑ Executive review and budget harmonization



# Justifying the Appropriateness of the Payment

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- ❑ What was the HCP compensated to provide the service?
  - Does the company have a standard rate schedule
  - How was that developed
  - Is it used company-wide or only for certain functional areas
- ❑ What factors were considered in compensating for the service?
  - HCP specialty
  - HCP stature
  - Level of effort
  - Level of “intensity”
  - Deriving an hourly rate
- ❑ How were those factors validated?

# Implementation Considerations for FMV

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- ❑ Managing budget constraints across different functional areas that may yield varying payment levels:
  - Sales & Marketing
  - Clinical Research
  - Medical Affairs
  - Professional Education
  
- ❑ HCPs may have a perceived value of certain services and may be willing to accept a lower level of payment
  - Downstream clinical or medical value
  - Support for medical education and the medical mission

# Key Take Away Points

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- ❑ Companies should consider developing a cross-functional team to review requests for HCP services.
- ❑ The service requests should have some documentation of strategic objective and business need.
- ❑ Implementation of an FMV schedule should consider the contracting needs of all functional areas to ensure harmonization of payment.
- ❑ Gaining buy-in from the key stakeholder is critical to building a successful and sustainable process.
- ❑ Consider developing a guidelines document.



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