



Processes and Policies: Documenting & Ensuring FMV Compliance

Presentation and Panel Discussion:

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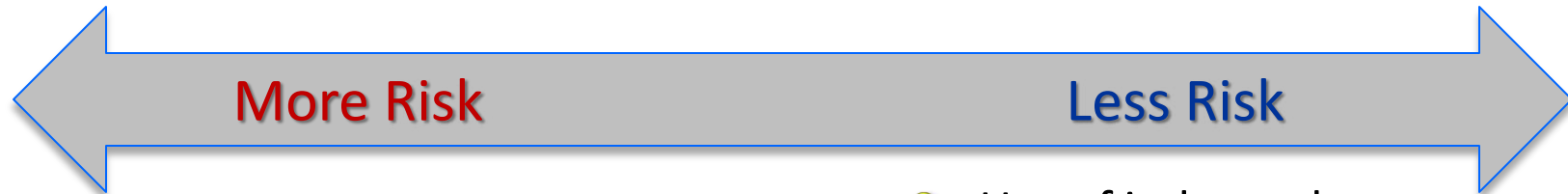
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Healthcare Professional Compensation: A Global Issue

- New regulations, focusing on requirements for transparent interactions between life sciences companies, physicians and other types of healthcare providers are being implemented by governments and industry associations throughout the world.
 - Country specific transparency laws (*e.g.*, U.S., U.K., France, Slovakia, Netherlands, Japan, Australia)
 - Organizational codes of ethics (Eucomed, AdvaMed, PhRMA, IFPMA, EFPIA, etc.)
- Implementation of anti-corruption laws that include significant penalties for non-compliance, even when the violations occur outside of the country's geographic boundaries (*e.g.*, the U.K. Bribery Act, the U.S Foreign Corrupt Practices Act ("FCPA")).

The Healthcare Valuation Risk Continuum



- No formal valuation process
- Payment rates are based upon:
 - Market surveys of what other life sciences companies are paying
 - Physician “demands”
- Lack of documentation

- Use of independent credentialed appraiser
- Strict compliance with FMV definition
- Formal documentation process
- Use of accepted valuation approaches
- Application market data is free from bias
- Logical, defensible, reproducible conclusions



HCPs = Healthcare Provider/ Professional

- Can include physicians, nurses, technicians, pharmacists, academic researchers, administrators, etc.)
- Range in expertise and experience from local-level provider to international-level expert
- Valuation is based on specialty / job class and determined level (*i.e.*, tier).
- Valuation can be applied to all HCPs within the specialty / job class (*e.g.*, all nephrologists)

KOLs = Key Opinion Leaders

- Generally does *not* include nurses, technicians, most types of administrators
- Requires a level of experience and/or expertise that is (i) greater than an international level HCP or is (ii) extremely rare or unique
- Valuation is based on specialty, the unique expertise/experience of the individual KOL, and the responsibilities of the position they will be engaged to perform
- Valuation is specific to the individual

General Types of Arrangements with HCPs/KOLs



- Speaking engagements (*e.g.*, training, promotional presentations, etc.)
- Educational programs
- Surgical demonstrations
- Participation on advisory boards
- Consulting (*e.g.*, product direction, design, regulatory approval process, guideline development, etc.)
- Clinical trials (*e.g.*, principal investigator, etc.)
- Licensure / royalty arrangements

Factors to Consider: Assessing the FMV of HCP/KOL Compensation



- Compensation earned by a physician in his or her specialty practice may not be directly comparable to the compensation associated with providing services to medical device, biotechnology, or pharmaceutical companies.
- The determination of FMV compensation should be based on an objective and consistent methodology based on:
 - The individual HCP's/KOL's experience and expertise;
 - The specific requirements of the company, product group or department engaging the HCP/KOL;
 - The HCP's/KOL's clinical specialty;
 - The specific services contemplated under the arrangement; and
 - The time requirements of the position.

Determining the FMV of HCP Compensation: *Stratification Models*

- Stratification models are used to classify HCPs into homogeneous groups (*i.e.*, tiers) based on level of expertise and experience.
- Typically, U. S.- based HCPs are classified using a four (4) tier stratification model:
 - International level (Tier I)
 - National level (Tier II)
 - Regional level (Tier III)
 - Local level (Tier IV)
- More granular stratification models, with 8-10 tiers may also prove to be useful in certain circumstances

Determining the FMV of HCP Compensation: *Stratification Models*



- Non- U.S. HCP stratification models generally include fewer than 4 tiers
- Stratification model classification criteria (the “Attributes”) are dependent on the specific expertise/experience requirements of the company, product group, department engaging the HCP.
- The HCP’s CV is the typical source for information.
 - *CVs can vary widely in terms of content...*
 - *Other sources of documentation of a HCP’s expertise and experience may be required...*



● ***Change can be difficult...***

- Explaining the process

● **Data gathering**

- Who to include?
- Clearly defining what you need to know
 - HCP/KOL Specialties and Types?
 - What are their roles... ? Why are they engaged?
 - What characteristics (Attributes) are important when you select an HCP for a particular role/engagement?
 - Prioritizing the characteristics based on the HCPs role

Building and Testing the Stratification Model



- Each Attribute should be structured so that it can be answered on the basis of information provided in the HCP's curriculum vitae ("CV") or some other standardized document.
- Determine the value/weight of each Attribute based on information provided during interview process
- Test the stratification model against sample CVs
- Allow key constituents the opportunity to test the model and provide feedback
- Iterative process
- May need more than one stratification model

Determining the FMV of HCP Compensation

U.S. – Based HCPs: General Guidelines

- Develop stratification model including Attributes and weighting structure.
- Using data from multiple surveys, identify compensation for each identified HCP clinical specialty.
- Use multiple sources of compensation data and ensure adequate sample size.
- Consider survey compensation across multiple years to normalize anomalies.
- Adjust for benefits (*i.e.*, with recognition that the identified HCPs will be independent contractors), and determine the upper end of the compensation range.
- Determine hourly compensation range for professional services within each stratification tier.
- Determine hourly compensation for *travel* and other similar non-professional activities.

Determining the FMV of HCP Compensation

Non-U.S. Based HCPs: Issues to Consider

- HCP CVs tend to be less detailed/complete than U.S. counterparts;
- Educational and training differences in each country;
- Number of required stratification tiers may vary in different countries (*e.g.*, in less developed countries there may not be a need for more than 2 tiers, while in more developed countries, 4 tiers may be more appropriate);
- HCP compensation systems vary widely ... employed, private practice, hybrid;
- Wide differences in compensation between rural HCPs and those providing services within large cities ... especially true in less developed countries;
- Available compensation data may be biased and outdated;
- Available data may only be reported for one statistical interval, *e.g.*, the median

Determining the FMV of HCP Compensation

Non-U.S. Based HCPs: Issues to Consider (cont.)

- Lack of compensation data (surveys) by clinical specialty;
 - Identified compensation data for a “generalist” or “specialist” can be made more granular (*e.g.*, cardiac surgeon, orthopedic surgeon, oncologist, etc.), by applying an “Adjustment Factor”
- Compensation data available for HCPs residing and working in other countries, may not be current and may need to be converted to current rates through the application of a CPI adjustment;
- *Just because a country is part of the European Union doesn't mean HCPs are compensated at the same rate in each country...*

Panel Discussion



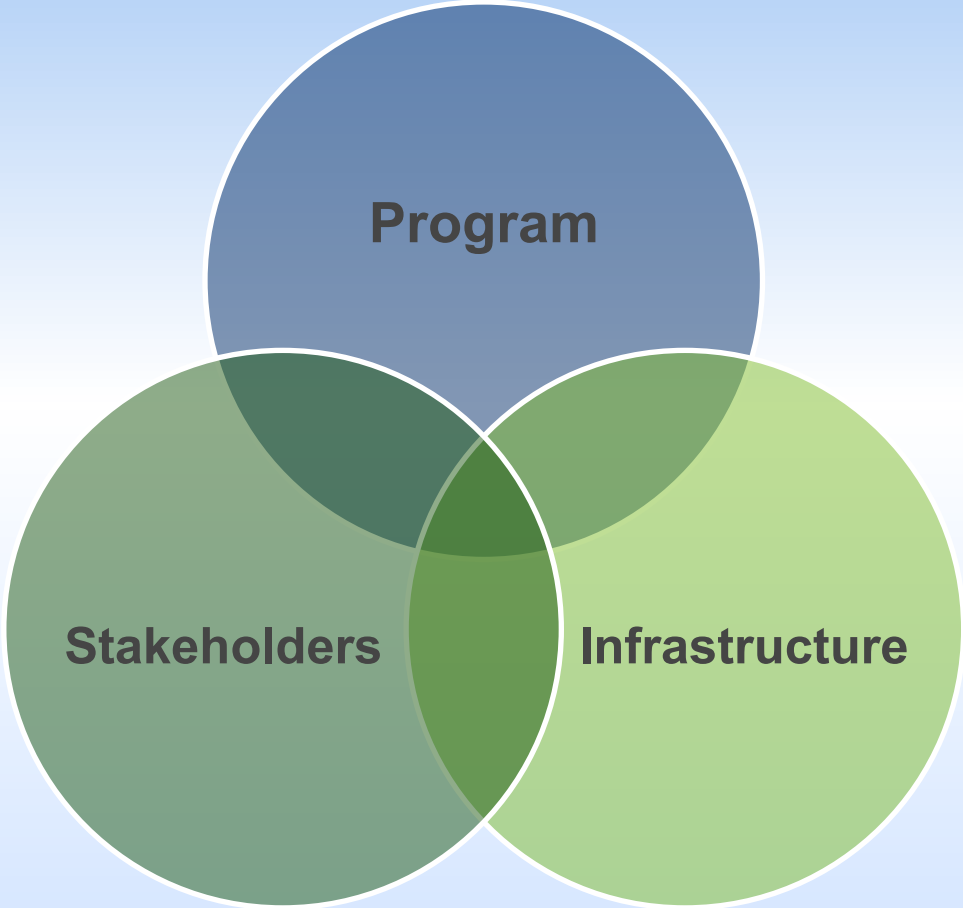
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Lessons Learned from Developing & Implementing a Global, Enterprise-Wide, FMV Compliance Compensation Plan

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Drivers of Success



Successes & Lessons Learned

Don't assume anything- verify assumptions

Don't build from the Ivory Tower

Solve for the 80% not the 20%

Sometimes you have to go slow to go far

Pilot Pilot Pilot

