

The First International Medical Device Compliance Congress

Benchmarking Your Firm's Global Practices in Fraud and Abuse and Compliance

Globalization of Fair Market Value

Developing Standards and Guidance for Affiliate Countries

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Today's Discussion Agenda

Section I

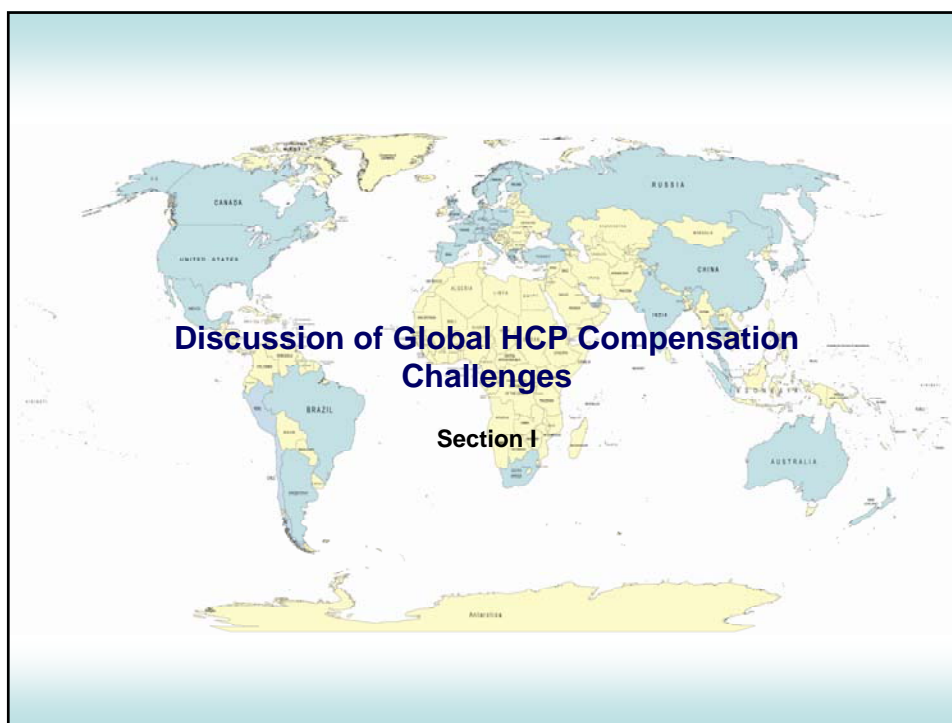
Discussion of Global HCP Compensation Challenges

Section II

Developing Compensation Guidance

Section III

Real World Implementation Considerations



Scrutiny of Physician Industry Relationships

Evaluating the Appropriateness of Payments

- Industry relations with healthcare professionals (“HCPs”) are under significant scrutiny around the globe.
- Regulatory authorities are concerned about the nature of the industry’s relations with HCPs and the ability of payments and affiliations by the industry to influence the medical decision making process.
- Most regulatory authorities cite the need for the industry to ensure that the services they engage from HCPs are for “bona fide” purposes and that industry uses standards of “reasonableness” in their payments to HCPs for those services.
- Regulatory authorities generally provide limited guidance on what is considered a “reasonable” payment to an HCP.
 - In some cases, regulatory authorities will cite the national health service reimbursement schedule as a reference point.
 - The industry must self-assess “reasonableness” in determining payment amounts to HCPs.

The Core Business Issue

Evaluating the Appropriateness of Payments

- Companies need to develop standards and processes to address their international affiliates' contracting needs for HCPs.
 - Affiliates will generally engage HCPs from other affiliate countries.
 - Without standards and processes regarding how to engage HCPs within an affiliate country or between affiliate countries, companies risk violating country-specific codes regarding payment to HCPs.
- Standards should address documenting and demonstrating the “bona fide” need of an affiliate to engage an HCP either within the country or from another affiliate country.
- Additionally, standards should address the “reasonableness” of payment levels to HCPs by either providing direct guidance on the payment or providing guidance on how payments should be determined.
- Processes should also address how HCPs should be engaged and paid and provide guidance on the engagement of HCPs that are employees of the public health service or government institutions.

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The Standards for Analysis

“Reasonableness” vs. Fair Market Value

- Most regulatory authorities provide some guidance regarding standards for payments to HCPs for services or reference established standards.
- The U.S. has one of the most stringent standards regarding compensation to HCPs and the standards are set and enforced at both the federal government level and the state government level.
- Various regulations and associations in the U.S., including the U.S. Internal Revenue Service (Taxation Authority) and various professional associations (AICPA, ASA, NACVA, etc.), have defined *Fair Market Value*:
 - “The price at which a good or service would trade hands between a willing buyer and a willing seller neither being under any compulsion to buy or sell, and both having reasonable knowledge of all relevant facts as of the date of valuation.”
- Comparatively, most regulatory authorities outside of the U.S. reference a standard of “fairness” or “reasonableness”.
 - The standard requires less rigor and provides medical device manufacturers with some flexibility in developing standards for payments.

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Developing a Compensation Framework

Providing Guidance on Engaging and Compensating HCPs

- Regulatory authorities around the world tend to follow a set of general parameters regarding engaging and compensating HCPs:
 - Payment should be based on the individual HCP's time and effort in providing the service to the medical device manufacturer.
 - Services should be of a strict scientific nature and in support of the company's core product lines and disease categories.
 - A service agreement should be in-place between the company and HCP in advance of any services being provided.
 - Special care should be taken when engaging HCPs that are associated with a government-operated facility such as a hospital or university.
- Developing agreements and setting compensation:
 - Service agreements should clearly outline the business objectives and the services/activities that are to be provided by the HCP.
 - Compensation should be clearly outlined, based on the activity.
 - HCPs that are employees of a hospital or university should have specific release.

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Addressing the Data Challenge

Analyzing Various Data Sources for Compensation Benchmarks

- Finding appropriate benchmarks for compensating HCPs for their time and effort may be difficult based on the country.
- Generally, HCP salaries are a good benchmark from which to base payments for medical device company expert services such as consulting and speaking.
- Obtaining HCP salary information is not always easy and the availability varies by country.
- The respective national health service physician fee schedule data may also be a reasonable benchmark for the value of an hour of time.
 - Adjustments should be made based on “cash” vs. government reimbursement
 - An HCP’s “opportunity cost” should also be measured
- Marketing and field sales personnel can also provide benchmarks based on discussions with HCPs; however, those references should not be the primary source from which payment schedules are derived.

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Operational Hurdles in Developing Compensation Guidance

Addressing Nuances by Affiliate Country

- There is no “one size fits all” analysis that will address the needs of all affiliate countries.
- Developing a list of standardized services could be difficult and may require significant discussion with managers at each affiliate.
- Companies must assess if compensation guidance will be at the affiliate level or broader to include multiple affiliates.
 - In general, developing guidance that is too broad may risk over-payments to HCPs in some countries and under-payments to HCPs in other countries.
 - However, developing HCP compensation guidance at the affiliate level could be a significant undertaking for an organization.

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Developing Compensation Guidance

Addressing Variations in Services and HCP Types

- Standardization of Services:
 - Consulting services for sales and marketing
 - Participation in advisory boards
 - Venue-based clinical presentation (typically over dinner)
 - Office-based clinical presentation (typically over lunch)
 - Presentations to company personnel
 - Scientific talks at conferences and symposia
 - Consulting services related to clinical data or clinical trials
 - Publications and authorship
 - Design team participation
- Developing HCP Segmentation:
 - MD vs. non-MD
 - Varying payments by stature (Global Luminary, Key Opinion Leader, Regional Thought Leader, Community Practitioner, etc.)

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Global Compensation Challenges

The Economic Environment of Affiliate Countries

- Global events where HCP participants may be present from various affiliate countries may pose a specific difficulty if HCP compensation varies by individual.
 - Paying HCPs differently for attending the same event may cause friction among the participants.
 - However, providing the same level of payment for participants around the world may not meet the regulatory guidance of the respective affiliate country.
- Consideration should be given to the economic conditions and cost-of-living index of the affiliate country:
 - The cost-of-living and annual income will vary broadly by affiliate.
 - Although key economic metrics may be more closely aligned by region, organizations must evaluate the specific situations by affiliate country in the decision making process.
 - In developing countries, payments by medical device manufacturers may account for a significant portion of an HCP's total annual income.

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Standardizing Services Being Engaged

Developing a Standard Framework for HCP Services

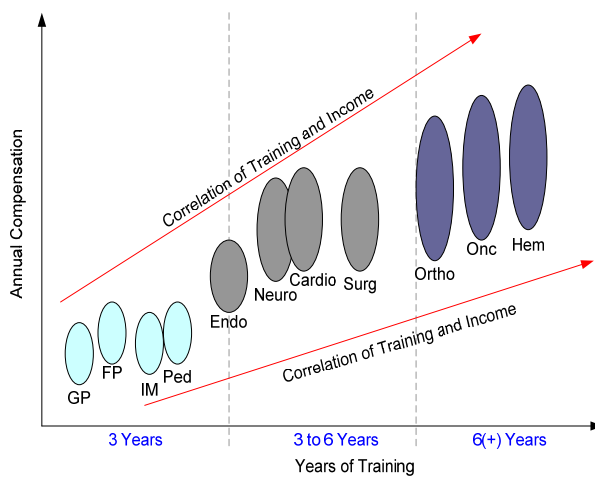
- Manufacturers should develop a standard framework through which they can assess HCP services and provide guidance on compensation:
 - Preparation time
 - Travel time
 - Service time
- Develop standard assumptions and nomenclature for services to facilitate engagement of HCPs by affiliate countries.
 - Short clinical programs
 - Speech at congress/symposia
 - Advisory boards
- Provide affiliates with guidance regarding addressing issues with international travel.
- Provide guidance with supplementary programs (advisory boards, symposia, etc.) that may be associated with major congresses.

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Addressing Variations in Physician Compensation

Developing a Manageable Segmentation Strategy



Considerations

- Years of HCP training and compensation are correlated
- For large manufacturers, segments by individual specialty may not be feasible
- Appropriate groupings of HCPs should be assessed
- Large variations may occur within specialties requiring guidance regarding HCP stature and influence

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Real World Implementation Challenges

Harmonizing Services and Payments Across the Globe

- Gaining Consensus on Services
- Gaining Consensus on HCP Segmentation
- Developing a Differential Compensation Strategy
- Developing Compliance Policy on Engagement of HCPs
- Training

Gaining Consensus on Services

Developing a Data Gathering Strategy

- Developing a standard reference for various service activities will require discussion and input from each country affiliate.
- Obtaining information may be a significant challenge among affiliates.
- A compliance or marketing lead should be identified in each affiliate to “shepherd” the process.
- Data can be gathered through teleconferences, surveys, or face to face meetings.
- Once all input is gathered, some type of consensus discussion should be organized to confirm assumptions and preliminary analysis.

Sample Survey Illustrative Purposes Only

Question	Response
1. How many years of experience do you have in the field of [Service]?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
2. How many years of experience do you have in the field of [Service] in your current role?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
3. How many years of experience do you have in the field of [Service] in your current role in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
4. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
5. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
6. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role in your current country in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
7. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role in your current country in your current country in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
8. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role in your current country in your current country in your current country in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
9. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role in your current country in your current country in your current country in your current country in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years
10. How many years of experience do you have in the field of [Service] in your current role in your current country in your current role in your current country in your current country in your current country in your current country in your current country in your current country?	1-5 years, 6-10 years, 11-15 years, 16-20 years, 21+ years

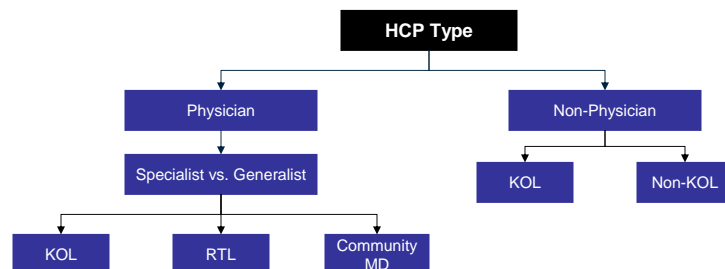
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Gaining Consensus on HCP Segmentation

Standardizing Nomenclature and Nomination

- Identify the appropriate HCP segments being utilized by all affiliate countries and develop standard nomenclature and definitions.
- Develop a process through which individual HCPs will be qualified for one of the established segments.

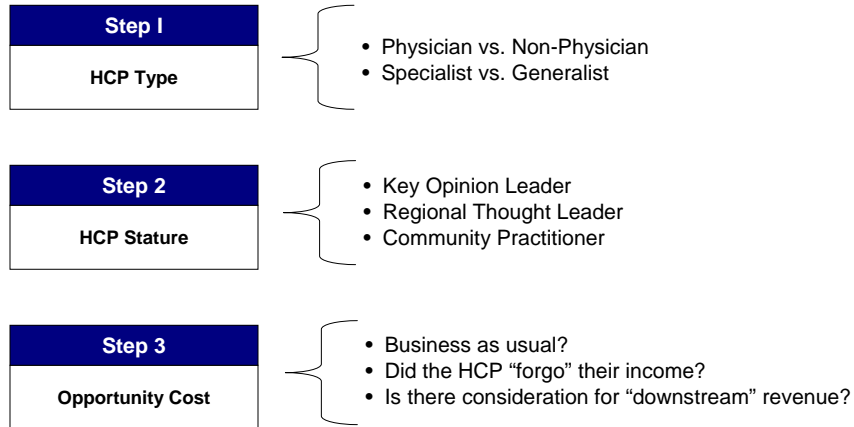


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Addressing Differential Compensation

The Concept of "Opportunity Cost"



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Developing a Basis for Compensation

A Multi-Step Process for Providing Guidance on Payments

Basic Calculation = Level of Effort ("LOE") for the HCP x Base Rate

- **Level of Effort** is the aggregate time spent by the HCP in preparing for the service activity, traveling to and from the activity, and the time spent performing the activity.
- **Base Rate** is determined by the categorization of the HCP relative to the segmentation scheme, the compensation levels associated with that HCP segment, and any relevant premiums that may be assigned to the compensation data.

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Questions?

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