

Cross-Border HCP Engagements: Factors to Consider

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Topics

1. What is a Cross-Border HCP Engagement?
2. Issues Associated with Cross-Border Engagements
3. Recommended Approaches

What is a Cross-Border HCP Engagement?

The retention of an HCP from one country to provide a professional service for a part of the company based outside the HCP's home country (e.g., HQ or a business unit based in another country), or the retention of an HCP by the home country business unit to provide a service for that business unit in another country.

Issues Associated with Cross-Border Engagements*

Compliance with applicable policies, procedures, laws, regulations and codes, including pre-notification requirements, for the HCP's home country and the country where the service is being rendered.

Appropriate Fair Market Value (FMV) determination.

Determining who will be Company's contracting party and use of appropriate Professional Services Agreement (PSA).

Proof of Service and Payment.

Document Retention.

Meeting relevant transparency reporting requirements.

How to do this in an efficient manner?

*Note: This assumes a legitimate need for a professional service exists and proper selection of a qualified HCP(s) to perform the service.

Compliance with Applicable Laws, Regulations and Codes

- Policies, Procedures and Associated Training should exist that set forth each country's requirements for retaining HCPs for professional services.
- HCP home-country requirements and those of the country where the service is being provided must be reviewed.
- These should include all relevant requirements, such as obtaining regulatory body or employer pre-approval.
- A local point(s) of contact should be identified for each country to answer questions and a determination must be made as to what function should provide this resource.

Appropriate FMV Determination

- Each country should have FMV “grids” based on appropriate methodology and rate information.
- Local medical staff should be actively involved in establishing the methodology and rates. The rates should be updated on a regular basis to reflect current values and approved by Medical.
- The FMV grid should be available in the local language and English and be easy to use.
- Companies should consider establishing and applying one FMV methodology, providing consistency as appropriate regarding number of tiers of HCPs based on level of expertise, how to address HCP travel, etc.
- A process must be established for review and approval of FMV exceptions and they must be based on legitimate reasons.
- Documentation of FMV determined should be maintained.

Use of Appropriate Professional Services Agreement

- ✓ Each country should have a PSA template prepared by legal that meets local requirements.
- ✓ PSA should provide clearly all services to be rendered (including preparatory work, active work, post work), fees to be paid for professional services (based on FMV) and also should provide for reimbursement of reasonable travel related and incidental expenses.
- ✓ Payment should be predicated on services actually being provided.

Proof of Service and Payment

- Appropriate proof of service should be obtained before payment is made.
- Proof of service may vary depending on nature of professional service provided and local requirements.
- Documented proof of service should be maintained as part of documentation associated with the retention.

Meeting Relevant Transparency Reporting Requirements

Payments made for services rendered and other amounts paid/reimbursed for travel and appropriate incidental expenses must be tracked for publication/reporting pursuant to applicable transparency laws.

Document Retention

- Key documentation associated with retention of HCP, performance of service and payment should be maintained together for easy access.
- Should have established document retention approach, whether in local offices in HCP home country; business owner's department files; or both.
- Documents should be complete and easily accessible if needed (e.g., Corporate Audit, etc.).
- Consider preparing a checklist to help ensure appropriate documentation is created and retained.

How To Do This In An Efficient Manner

- Create Center(s) of Excellence staffed with people whose role it is to facilitate all aspects of HCP retention and ensure it is done in a compliant manner and appropriate documentation is completed and maintained in central repository. This also reduces administrative burden on business owners.
- Publish all country policies, procedures, FMV grids, template PSAs, etc. in a computer-based tool that all employees globally can access:
 - ✓ Keep updated
 - ✓ Identify function(s) responsible for keeping updated.

How To Do This In An Efficient Manner? (cont'd)

- Identify local point(s) of contact to help with questions and with local regulatory submission requirements.
- Train Center of Excellence staff to use the computer-based resource to access local requirements so the staff can be as self-sufficient as possible.
- Consider identifying and deploying computer based solution that any employee can access to determine appropriate FMV for an HCP in any country, document that FMV determination and retain it.
- Interactive training of all relevant stakeholders.
- Communicate well and be collaborative.

QUESTIONS?

