FMV & KOL Evaluation Solutions
Agenda

Welcome

Why FMV is Critical to the Compliance Program

Common Challenges in Implementing KOL Tiering and FMV

Strategies for Implementing Integrated FMV and KOL Tiering Methodologies

Polaris Business Process Outsourcing Solution for KOL Tiering
Looking at 2016 & beyond - Polaris partners with clients to understand emerging compliance risk trends

1. Increased global focus on transparency, fair market value, and anti-bribery anti-corruption
   
   *Demonstrates that enforcement agencies and the public are concerned with financial transparency which also implicates…*

2. Concerns of the rising cost of healthcare, and specifically the rising cost of pharmaceutical products
   
   *Increasing price concerns will affect the industry’s relationships with major customer groups, so…*

3. Greater scrutiny will be placed on fee for service engagements with customers
   
   *These arrangements may cause violations of the law that could have been prevented by…*

4. Proactive Compliance Risk Management will be critical
   
   *Pharmaceutical manufacturers must be risk intelligent in executing global commercial strategies*
What is FMV and why is it important?

- **Definition of Fair Market Value (Merriam-Webster)**
  - “A price at which buyers and sellers with a reasonable knowledge of pertinent facts and not acting under any compulsion are willing to do business”

- **OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers:**
  - “Payments for research services should be fair market value for legitimate, reasonable, and necessary services.”
  - “In general, fair market value payments to small number of physicians for bona fide consulting or advisory services are unlikely to raise any significant concern.”
  - “Manufacturers should periodically review arrangements for physicians’ services to ensure that… the compensation is at fair market value…”

FMV Analysis & Engagement ensures commercially reasonable & viable business decisions.

Compliance
## Common challenges include both business and compliance concerns

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Risk / Concern</th>
</tr>
</thead>
</table>
| • Too many KOL tiers | • Can make the process of tiering KOLs inefficient and also adds to the complexity of the tiering criteria  
• Ensuring consistency as you scale becomes more difficult |
| • Lack of tiering criteria to support definitions | • The first step is to define your KOL tiers, secondly you must establish objective and measurable criteria for each |
| • Failure to maintain auditable records for tiering | • The determination of KOL tier directly determines the level of compensation, and as such should be a part of your auditable record for HCP engagement |
| • Using global rates | • FMV is a local challenge and is locally determined  
• An argument can be made for some specialties and geographic regions to establish global minimum rates for the highest tier KOLs |
| • Confusing KOL tiering from nomination & selection | • There is a process for engaging HCPs and these 2 components are separate – 1) KOL tier objectively measures expertise, while 2) HCP nomination & selection is influenced by our relationship |
| • Not paying consistent fees for common services | • Controlling the rate used to contract HCPs does not ensure consistent application, the service must be valued (in hours) in order for the compensation to be consistent |
| • Tiering criteria that does not support effective measurement of non-MD consultants | • Criteria often do not differentiate MDs and PhDs from other consultants such as RNs, pharmacists or payer executives, resulting in impractical application of criteria or potentially underpaying for level of expertise |
Polaris Fair Market Value methodology is based on four key principles

1. Pay market rate for consultant’s time not for the value of the service
   • Since paying for time, rates should not vary based on type of service

2. Assure methodology supports higher fees for higher expertise
   • Required to pay “Thought Leader” higher fees

3. Create an effective process for evaluating physician expertise and determining “Thought Leader” status (i.e. Local, Regional, National, etc.)
   • Required to avoid kick-back allegations

4. Ensure all elements of the fee determination are grounded on objective and transparent data analysis

FMV methodology designed to be:
Flexible, Consistent, Objective and Auditable
Our “FMV Mantra”

Flexible – flexible model that recognizes ability to pay higher fees for higher degrees of expertise

Consistent – simple model that allows for efficient application

Objective – specific and measurable criteria for determining tier

Auditable – maintain auditable records to support rate determination
### FMV and compliance considerations

<table>
<thead>
<tr>
<th><strong>Anti-Kickback Statute</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main objectives</strong></td>
</tr>
<tr>
<td>- Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business</td>
</tr>
<tr>
<td><strong>How it relates to FMV?</strong></td>
</tr>
<tr>
<td>- Violation may be avoided by meeting a “safe harbor” exception, which includes a requirement of <strong>FMV payments</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Stark Law</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main objectives</strong></td>
</tr>
<tr>
<td>- Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies</td>
</tr>
<tr>
<td><strong>How it relates to FMV?</strong></td>
</tr>
<tr>
<td>- Most Stark Law exceptions include the requirement of <strong>FMV payments</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>False Claims Act</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main objectives</strong></td>
</tr>
<tr>
<td>- Prohibits knowing submission of false or fraudulent claims for payment to the federal government</td>
</tr>
<tr>
<td><strong>How it relates to FMV?</strong></td>
</tr>
<tr>
<td>- Violations of Anti-Kickback and Stark may give rise to actions under the FCA, and as stated above, one way to avoid the violations would be that payments are within <strong>FMV range</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Foreign Corrupt Practices Act</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main objectives</strong></td>
</tr>
<tr>
<td>- No improper payments/gifts to foreign officials</td>
</tr>
<tr>
<td>- Requires maintaining accurate records and internal controls for financial reporting purposes</td>
</tr>
<tr>
<td><strong>How it relates to FMV?</strong></td>
</tr>
<tr>
<td>- Violation may be avoided by making consistent <strong>FMV payments</strong> and accurate recording of those payments</td>
</tr>
</tbody>
</table>
There are THREE equally important elements of FMV and each are necessary

- **FMV Rates**
- **Tiering Model**
- **Activity Fees**

While FMV rates based on objective data are a key control in the HCP engagement process they need to be supported by robust tiering models and consistent activity fee practice:

- Compensation data used for FMV represents national averages
  - Industry not routinely engage “average” physicians

If you compensate based on tier, without a standard methodology it is difficult to ensure consistency:

- If you lack consistency, the control is **not** working
- Depending on your rate methodology the overpayment could be 20% - 80% depending on country and specialty

FMV as a risk control is also strengthened if companies pay similar fees for similar activities based on standard service level expectations
Business case for implementing FMV rests on three principles

- **Competitiveness**
  - Compensation within FMV range will help retaining world-class/first tier HCPs
  - In turn, their expert knowledge will lead the company to remain competitive in the market
  - Also, cost saving will result from efficient contract processing, which can be re-directed to other departments or expenditure types for more resourceful usage

- **Consistency**
  - Having the FMV rate cards for applicable HCPs, company can ensure that the payments made to the HCPs are consistent within the same level of expertise and specialties
  - Consistent payments to HCPs will also reinforce the business relationship with them.
  - For example, if HCPs with same level of expertise/specialty attending the same advisory board are being paid consistently, company can avoid risky situation where HCPs find out about different payment values which eventually can lead to end of business relationship

- **Efficiency**
  - Consistent FMV payments will help processing each contract fast and efficiently
  - It will also ensure that each contract made with an HCP is a viable business decision for the company
  - Vigorous and often exhausting negotiation process can be eliminated
A robust and consistent FMV program can drive cost saving and greater business process efficiency

- Incorporate consistent FMV practices in annual planning process
- Reduce overall spend on activities that may not require high remuneration
- Control cost for specific activities by setting contracting rates below FMV maximums

**Cost Savings Methodology**

Manufacturers should incorporate consistent FMV compensation practices in annual planning process as a means of reducing cost and gaining greater process efficiency:

- Cost can be monitored and reduced by setting FMV limits on the total amount spent on specific HCPs or activity types
- Overall budget planning can also be made more accurate thus reducing the need for ad hoc changes throughout the year which can be costly and detrimental to business objectives

Overall spend by activity can also be reduced by identifying activity types where high remuneration may not be required as part of the rate determination process:

- Those activities typically have a high non-monetary value to the participating KOLs where manufacturers may have significant leverage

Even for activities where the monetary value is critical to the KOL’s participation, companies can reduce cost through setting FMV below the maximum fee of individual activities where possible
Tiering of KOLs is based on level of expertise

Expert premiums designed to recognize that markets will typically compensate higher levels of expertise with higher levels of pay

Polaris methodology works with three tiers, defined on level of expertise, not on level of current earnings

- Local expert: associated with average to above average expertise
- National expert: well recognized in their field within their country but with only limited recognition (if any) in other countries
- International experts: top experts in their field (e.g. top 5-10% in a country)

Methodology for expert premiums (KOL)
Tiering HCPs for payment must be recognized as a separate process from identifying and selecting HCP consultants

HCP Selection Considerations

- Scoring model is not designed to facilitate the HCP selection process
- Selection legitimately focuses on criteria that are not appropriate to incorporate in the determination of FMV rates/fees, e.g.:
  - Prior experience with the HCP
  - Effective communication styles
  - Public profile / celebrity status
  - Ability to influence others

Expert Tiering Model

- Model designed to support tiered hourly rate structures
- Scoring model’s sole purpose is to objectively identify HCP’s level of expertise within their field
  - Expertise is the only basis that can be used to support tiered FMV fee structure
  - To maintain objectivity, criteria needs to be based on recognition of HCP’s expertise by their peers within their field
Effective expert tiering methodologies are grounded on objectivity, flexibility, and simplicity

### Three Pillars Of Successful Expert Tiering Methodologies

<table>
<thead>
<tr>
<th>Objectivity</th>
<th>Flexibility</th>
<th>Simplicity</th>
</tr>
</thead>
</table>
| • Objectivity needed to ensure that tiering assessments are consistent and not subject to significant business judgment  
  o Issue becoming more important with widening disclosure requirements | • Not all experts will have a similar career path or pattern of professional participation  
  o Successful model should capture physician expertise regardless of chosen career paths  
  • Model flexibility can facilitate appropriate tiering of non-traditional physicians | • Overly complex models create implementation that may limit access to certain HCPs or significantly lengthen time frame for evaluation  
  • Complex models do not easily lend themselves to outside review if necessary |
| • Models grounded on **peer judgment** of physician expertise to avoid bias  
  • Focus needed on expertise criteria and not selection criteria  
  • Criteria should assess concrete achievements that can be easily measured | • Expertise may be demonstrated in any of several categories  
  • Flexibility achieved by recognizing *expertise in one or more categories* but not necessarily all categories  
  o Require high standards in each  
  • Avoid breadth of recognition biases (i.e., accumulating modest achievement in many areas) | • Focus on **criteria readily available** in CVs or other routinely obtained documents  
  • Limited number of categories reflecting broad areas of HCP expertise  
  • Keep criteria simple and understandable |
KOL Tiering is based on objective evaluation of medical expertise

- Tiering grounded on identifying objective measures of peer recognized achievements
- For each physician, the tier is based on either cumulative points across categories or the highest tier documented in any one category, validated by the same or a higher score in a 2nd category
- Specific criteria are tailored for implementation globally

**Categories of Expertise**
- Employment
- Publications & Trials
- Speaking & Advisory
- Associations & Journals

**Tiering for KOLs**

**Scoring Model for Expert Status**

**Exceptions:**
- Determined based on facts and circumstances

**Tier 1:**
- Top expert in a country

**Tier 2:**
- Significantly above average expertise, broadly recognized by peers

**Tier 3:**
- Average to above average expertise
Tiering methodologies vary by company, but based on one of two basic model formats

<table>
<thead>
<tr>
<th>Categories model</th>
<th>Cumulative points model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four broad categories of HCP expertise comprise the framework of this scoring</td>
<td>Points accumulate across undefined number of categories</td>
</tr>
<tr>
<td>model</td>
<td>Tier is determined based on highest number of points awarded across all categories</td>
</tr>
<tr>
<td>Overall tier is aligned with the second highest score of four categories</td>
<td>and criteria</td>
</tr>
<tr>
<td>Prescriptive model focused on only highest achievement per category</td>
<td>Multi-select of all applicable criteria across categories</td>
</tr>
<tr>
<td>Conducive to consistent tiering</td>
<td>Varying application of criteria</td>
</tr>
<tr>
<td></td>
<td>Breadth of recognition biases</td>
</tr>
</tbody>
</table>

Each model is simple, flexible and objective → Effective!
What criteria should be used

Clinical experience
• Years of Experience in Specialty
• Leadership in hospitals or healthcare settings
• Leadership/Membership in Professional & Scientific Society
• Leadership/Membership in Guideline Committees or Official Committees
• Board Certification or Additional Academic Degrees or Fellowships

Research
• Number of Peer Reviewed Publications
• Number of Peer Reviewed Presentations
• Leadership/Membership in Research Institution
• Leadership/Membership in Editorial Boards of Journals / Periodicals

Academia
• Years of Experience in Teaching
• Leadership in Universities or Teaching Institutions
• Supervision of Graduate / Post-Graduate Students
Internal stakeholders buy-in needs to be facilitated through a robust training and implementation process

- Internally approve FMV rates and KOL methodology
- Confirm responsibilities and ownership of tiering process
- Draft FMV supporting documentation (policies, SOPs, FAQs)
- Train stakeholders on rates and methodologies
Critical tiering considerations

- Develop objective and repeatable criteria to be used in evaluating HCPs and placing them in appropriate tier
- Base decisions on information contained in CVs provided by the HCP
- Define criteria in a manner that allows for consistent “scoring” across multiple individuals in HCP team
- Seek out business input and “buy-in” to process
- Training is key!
Polaris’ process for KOL tiering is the “easy button”

- HCP search & request
- Data intake & validation by Polaris
- Expert review of CV for tier and specialty
- Document results
- Report results

Benefits to Outsourcing with Polaris

- Subject matter expertise
- Scalable resourcing
- Records management
- Privacy controls
- Seamless flow of transactions
- Training and change management
- Cost effective engagement model
Additional FMV considerations and emerging risks

Common industry challenge in addressing FMV questions surrounding the use of medical equipment as part of equipment rental programs
• Polaris has extensive experience in assessing the value of these rental programs as well as assisting clients in mitigating the inherent compliance risks associated with the use of rented or loaned medical equipment by physician practices

Fees paid to hospitals in order to conduct training activities or medical equipment demonstrations are also increasingly being assessed for FMV
• Those fees may include credentialing fees or other administrative charges levied by hospitals
• Important to evaluate fees particularly in countries with government ownership of medical facilities

Support for research activities should also be evaluated for FMV in order to determine the reasonableness of the requests
• Many companies focused on creating standard FMV processes for such requests focused on developing benchmarks for core cost items as well as ad hoc evaluation of individual requests
• Important to be able to stratify requests based on inherent risk profile driven by factors such as total amount requested, type of requesting entity, amount of supporting documentation provided etc.

Market access fee for service arrangements are also becoming more common with FMV as a key consideration for such activities
# Contact information

<table>
<thead>
<tr>
<th>Name</th>
<th>Darren Jones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td>Partner</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:DJones@polarismanagement.com">DJones@polarismanagement.com</a></td>
</tr>
<tr>
<td>Phone</td>
<td>O: +1.646.381.8974</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Jodi Cianciotto</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td>Director, Global Support and Business Process Outsourcing</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:jcianciotto@polarismanagement.com">jcianciotto@polarismanagement.com</a></td>
</tr>
<tr>
<td>Phone</td>
<td>O: +1.646.599.8584</td>
</tr>
</tbody>
</table>
Darren Jones  
Partner

**Contact Information:**
Direct: +1. 646.381.8974  
Mobile: +1. 412.302.2978  
Email: djones@polarismanagement.com

**Areas of Expertise:**
- Compliance Strategy & Governance  
- Compliance Auditing & Monitoring  
- Process Design & Compliance Excellence  
- Global Anti-Bribery & Anti-Corruption Program Development

**Professional Experience:**
- Protiviti - Associate Director, Risk Consulting & Internal Audit  
- Schering-Plough – Supervising Senior Auditor  
- Arthur Andersen – Technology Risk Consultant  
- University of Pittsburgh, College of Business Administration – Adjunct Professor, Accounting Information Systems

**Education / Qualifications:**
- University of Pittsburgh, B.S.B.A – Accounting  
- Certified Internal Auditor (CIA)  
- Seton Hall Law School - Healthcare Compliance Certification

**Polaris Management Partners**
Darren is a Partner at Polaris Management Partners where he helps lead a global consulting practice dedicated to supporting client's compliance risk management needs. He has lead compliance consulting projects across all healthcare interaction risk areas, and has developing deep expertise in the commercial and medical activity areas. Darren has over 14 years of audit and risk consulting experience. He has extensive global audit experience, having executed compliance audits in numerous foreign countries in South America and Europe.

**Major Projects**
- Supported several pre-commercialization specialty pharmaceutical companies implement a compliance program covering all healthcare interactions by scientific, medical and commercial professionals.  
- Assisted a fast growing Oncology specialty pharmaceutical company develop compliant and effective business processes for all commercial and medical affairs operations prior to product launch.  
- Conducted numerous compliance risk assessment projects to establish compliance office priorities and a common risk awareness by management’s compliance committee and the board’s audit committee.  
- Collaborated with numerous clients to establish Key Risk Indicators (KRI) to monitor compliance program effectiveness and direct compliance oversight activities, including field monitoring.  
- Supported a client in redesigning processes for managing medical education and investigator initiated research grants.  
- Assisted a global top 10 pharmaceutical client by leading a team to develop fair market value compensations rates, as well as fees for common HCP engagement activities in over 70 countries. Our team also implemented a global platform for calculating FMV rates and fees.  
- Developed a methodology for assessing fair market value of engagements with customers including, wholesalers, specialty pharmacies, GPOs, payers, etc. Conducted FMV assessments of various services including reimbursement hotlines, medical information fulfillment, promotional activities and specialty product distribution.  
- Assisted a global top 10 pharmaceutical client in designing and implementing an audit strategy to assess wholesaler and specialty pharmacy compliance with sourcing and distribution contracts. The project provided assurance that product was sourced from and sold to legitimate end-users without “grey market” influences.  
- Managed compliance audits of pharmaceutical commercial and medical businesses in the United States and numerous international markets. The audit objectives were to ensure compliance with the global ABAC laws, various FDA and EMEA regulations

© Polaris 2016
Jodi Cianciotto
Director, Global Support and Business Process Outsourcing

Contact information
Direct: +1.646.599.8584
Mobile: +1.516.318.3244
Email: jcianciotto@polarismanagement.com

Areas of expertise
• Business Process Optimization
• Financial & Business Analysis
• Change Management
• KOL Methodology and Evaluations
• Transparency Reporting & Dispute Resolution

Professional experience
• Ernst & Young

Education / Qualifications
• New York University, Stern – M.B.A. (Operations Management)
• Cornell University – B.S. in Engineering (Operations Research & Industrial Engr)
• Six Sigma Champion

Professional accomplishments
• Employed process efficiencies around KOL methodology development and evaluation process design for major pharmaceutical manufacturers
• Conducted overhaul of internal business processes to promote transparency of internal operations, team performance and reporting

Polaris Management Partners and Polaris Solutions
Jodi leads the Business Process Outsourcing Group at Polaris and simultaneously serves as the Firm’s expert in internal business processes. She spent the first part of her career within Polaris as the director of operations, tasked with the responsibility of streamlining the business through the application of best practices. As someone who is adept in efficiency measures and deeply familiar with Polaris and all of its service offerings, Jodi has been able to identify outsourcing opportunities across our Management Partners and Solutions organizations and begin an aggressive growth trajectory for the BPO team. She has taken a group of isolated team members, created an intensive training process, cross-trained all individuals and created a lean, efficient and scalable business model.

Major Projects
• **Key Opinion Leader methodology**: Jodi has led several projects requiring methodology design, process evaluation and revamp for top 10 pharma companies. She also manages a team of KOL scoring experts, responsible for evaluating KOLs level of expertise. Her experience spans both medical and non-medical professionals, including Managed Market individuals in the U.S. and abroad

• **Funds Management Outsourcing**: Jodi leads a team of Grants Coordinators acting on behalf of several major pharma companies. She has extensive experience with process setup for new clients and revamp for efficiency of existing clients. She is responsible for full end-to-end grants management, inclusive of payment processing on behalf our clients

• **Transparency outsourcing**: Polaris’ transparency outsourcing offering includes third party data coordination, transparency reporting and dispute resolution project. This is a flexible offering and Jodi works with clients directly to evaluate the scope that best fits the individual client’s business needs. As the leader of this group, Jodi has experience managing such projects in the U.S. and is working to expand globally

• **Process Design**: Jodi created a suite of process maps, metrics, reports and SLAs for internal transparency, benchmarking and evaluation. She has worked extensively on both internal and client processes

© Polaris 2016