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Regulatory and Operational Issues in Implementing Global Enterprise-Wide HCP Compensation Plans in the Life Sciences

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Webinar Agenda

- Select Regulation of Payments to Health Care Professionals in the US and Abroad – **Jan E. Murray, Esq.**
- Key Considerations When Determining FMV Compensation for Health Care Professionals on a Global Basis– **Ann S. Brandt, Ph.D.**
- Lessons Learned from Developing and Implementing a Global, Enterprise-Wide, FMV Compliant Compensation Plan – **Colleen Evans**
- Questions & Answers

Select Regulation of Payments to Health Care Professionals in the US and Abroad

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Agenda

- New law on transparency in the life science industry
  - Payments to physicians and disclosure under the Patient Protection and Affordable Care Act of 2010 ("ACA")
  - Enforcement Initiatives
- Update on enforcement activity on US anti-corruption law and health care
  - Foreign Corrupt Practices Act (FCPA)
  - FCPA and Life Science Companies—enforcement

Agenda

- The laws that are the focus of this presentation should be understood in the context of other applicable law that also regulates payment to health care professionals, including in the US, federal and state Antikickback laws and the federal and state False Claims Act laws
  - Many countries have similar laws

Agenda

- Physician Payments Sunshine Act reporting obligations may reveal a financial relationship that implicates the Antikickback or False Claims Act laws
  - Very important to understand these underlying obligations although these are beyond the objective of this presentation
    - Antikickback Statute (see 42 USC §1320a-7b)
    - False Claims Act can reach those whose acts caused submission of a false claim (see 31 USC §3729)

Physician Payment Sunshine Act

- Physician Payment Sunshine Act—Overview
  - Section 6002 of the Patient Protection and Affordable Care Act ("ACA"), (Public Law 111-148)(Section 1128G of the Social Security Act)

    - Requires disclosure of payments made by pharmaceutical and device manufacturers and group purchasing organizations to physicians and teaching hospitals ("Covered Recipients")
    - Failure to report results in monetary penalties varying on whether the failure to report was "knowing"
    - Only applicable to payments made for ("Covered Products")
    - Covered Products are drugs, devices, biologicals or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program

Physician Payment Sunshine Act

- Shifting Reporting Deadlines
  - Final Rule changed the start date for the reporting of calendar year 2013 data to August 1, 2013 instead of the statutory start date of January 1, 2012 (42 CFR Parts 402 and 403)
  - CMS again modified the date and now manufacturers will complete a 2 step process: 2/18/14-3/31/14 manufacturers will register and submit "aggregate payment data" and sometime in May 2014 will be required to submit detailed 2013 payment data
  - All reported information will be published by CMS on a searchable public website

Physician Payment Sunshine Act

- Key Definitions—42 CFR Part 403
  - "Applicable manufacturer" – means an entity that is operating in the United States and falls within one of two categories:
    - (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply but not if such covered drug, device, biological, or medical supply is solely for use by or within the entity or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

Physician Payment Sunshine Act

- Key Definitions continued
  - (2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug device, biological, or medical supplies
  - "Applicable GPO" is an entity located within the US or doing business within the US that purchases or negotiates and arranges for purchase of covered drugs, devices, biologics or supplies for use by others that are reimbursed through Medicare, Medicaid or Children's Health Insurance Program (CHIP) and ordered by a physician

Physician Payment Sunshine Act

- Key Definitions continued
- "Covered Recipient" means a physician or a teaching hospital
  - "Physician" mean MD, DO, Doctor of Optometry, Chiropractors, Doctor of Dentistry and Doctor of Dental Surgery, Doctor of Podiatry; excepts physician employee of manufacturer
  - "Teaching Hospital" means a hospital that receives graduate medical education payments through Medicare including psychiatric hospitals that receive such payments

Physician Payment Sunshine Act

- Key Definitions—continued
- "Covered drug, device, biological or medical supply" means any of these for which payment is available under Medicare, Medicaid or CHIP either separately or through a bundled payment such as a DRG payment and:
  - if a drug or biological has to be ordered by a physician or
  - if a device, law must require premarket approval or premarket notification to the FDA.

Physician Payment Sunshine Act

- Reporting Obligation—Payment or Other Transfer of Value (42 CFR §403.904)
  - Direct and indirect payments or other transfers of value provided by applicable manufacturer to covered recipient and direct or indirect payments or other transfers of value provided to a third party at the request or designated by an applicable manufacturer must be reported to CMS on an annual basis
  - "Indirect payment or transfer of value" means payments or transfers where the applicable manufacturer "requires, instructs, directs or otherwise causes the third party to provide such payment or transfer of value to a Covered Recipient"

Physician Payment Sunshine Act

- What must be reported?
- For each payment or thing of value:
  - Name of the covered recipient (NPI, specialty, state professional licensure for physicians)
  - Address
  - Amount of payment or other transfer of value
  - Date of payment or transfer
  - Form of payment or transfer
  - Nature of payment or transfer
  - Related covered drug, device, biological or medical supply
  - Eligibility for delayed publication
  - Payment to third parties
  - Payments or transfers to physicians who are owners or investors
  - Additional information for context of payment

Physician Payment Sunshine Act

- CMS Requires Payment to be Reported by Category
  - Charitable contribution
  - Compensation for services other than consulting
  - Consulting fees
  - Current or prospective ownership or investment interests
  - Direct Compensation for speaker or faculty for medical education program
  - Education
  - Entertainment
  - Food and beverage
  - Gift
  - Grant
  - Honoraria
  - Research
  - Royalty or license
  - Travel and Lodging

Physician Payment Sunshine Act

- Reporting of Food and Beverages Values
  - CMS declined to increase a de minimus payment exclusion from a value of less than $10 and an aggregate threshold of $100 in calendar year 2013
  - Applicable manufacturer must calculate the value per person divided into the entire cost of food and beverage by the total number of individuals who partook in the meal including non-covered recipients

Physician Payment Sunshine Act

- Special treatment of research and continuing education payments
  - Payments or other transfers made in support of research (broadly defined to include basic and applied) made in connection with written agreement or protocol are covered by the law
    - Research payments are separately reported and the report may be delayed to protect manufacturer's intellectual property
    - Payments or other transfers in support of continuing education are not reportable if certain requirements are met

Physician Payment Sunshine Act

- Limitations on Reporting
  - Applicable manufacturer for whom total gross revenues from Covered Products constitute less than 10% of its total gross revenue during the fiscal year preceding the reporting year are only required to report payments that are related to Covered Products
  - Applicable manufacturers that qualify under common ownership by owner are required to only report payments that are related to Covered Products for which the entity provided assistance or support to the producers of the Covered Products
  - Applicable manufacturers that do not manufacture the Covered Product or do so only under a written agreement to manufacture the Covered Product for another entity and do not hold FDA approval, license or clearance are only required to report payments related to Covered Products

Physician Payment Sunshine Act

- Reporting Obligation—physician ownership and investment interests—42 CFR §403.906
  - Each applicable manufacturer and GPO must report annually all ownership or investment interests in the manufacturer or GPO that were held by a physician (or immediate family member) in the preceding calendar year
    - Must report name, specialty, NPI and dollar amount invested by each physician, value and terms of ownership or investment interest and direct or indirect payments or other transfers of value to the physician or a third party on behalf of the physician

Physician Payment Sunshine Act

- Penalties for violation (42 CFR Part 402)
  - $10,000 for each failure to report timely, accurately or completely a payment or transfer of a thing of value or an ownership or investment interest (up to $150,000 per annual submission)
  - $100,000 for a knowing failure to report up to $1,000,000 per annual submission

Foreign Corrupt Practices Act

- Foreign Corrupt Practices Act was passed by the US Congress in 1977 after revelations of extensive corporate corruption involving bribery of foreign officials (15 U.S.C.§§78dd-1, et. seq.)
  - Law has been amended since then to define certain defenses and to incorporate concepts from an international convention adopted by many US trading partners aimed at eliminating bribery of foreign officials

Foreign Corrupt Practices Act

- FCPA is organized around two major obligations
  - Anti-bribery provisions that prohibit bribing a foreign official to secure or retain business
    - Applied to both issuers of securities and domestic concerns and their officers, directors, employees, agents and shareholders
  - Record-keeping and internal controls
    - Very important obligations that include affirmative record-keeping requirements and submission of complete and accurate reports
- Both the US Securities and Exchange Commission (SEC) and the US Department of Justice (DOJ) have enforcement authority

Foreign Corrupt Practices Act

- What companies and individuals fall within the FCPA's purview?
  - Issuers of securities registered under Section 12 of the Securities Exchange Act of 1934 (1934 Act)
  - Those required to file reports with the SEC under Section 15(d) of the 1934 Act
  - May be foreign corporations

Foreign Corrupt Practices Act

- What companies and individuals fall within the FCPA's purview?
  - "Domestic concerns" mean:
  - Any individual who is a citizen, national or resident of the US
  - Any corporation, partnership, unincorporated organization, association, joint-stock company, business trust or sole proprietorship organized under the laws of the United States or its states and territories or that has a principal place of business in the US

Foreign Corrupt Practices Act

- What companies and individuals fall within the purview of the FCPA?
  - Officers, directors, agents, employees or stockholders that are acting on behalf of a covered enterprise or person
  - Applies to foreign nationals and foreign non-issuers (or non-domestic concern) that directly or indirectly engage in act to further a corrupt payment while in US territory

Foreign Corrupt Practices Act

- Foreign nationals and companies have been the target of many US enforcement actions
  - The largest FCPA action was against a German company, Siemens, and resulted in a fine of 800 Million (USD)
  - About 75% of total fines paid in 2011 were by foreign companies
  - Foreign national does not have to have been in the US to be subject to the law (e.g., SEC v. Straub, SDNY 2/8/2013)

Foreign Corrupt Practices Act

- What acts are prohibited?
  - Prohibits offer, payment, promise to pay or authorization of payment, gift, offer, or promise to give anything of value
  - With a corrupt motive
  - To a foreign official
  - To influence an action or decision in his or her official capacity, cause the official to take or forego an action in violation of a lawful duty, secure an improper advantage, or to induce the foreign official to use influence with the foreign government
  - To assist in obtaining or retaining for or with, or directing business to, any person

Foreign Corrupt Practices Act

- What acts are prohibited?
  - These same prohibitions apply to any foreign political party or official or any candidate for foreign political office
  - These same prohibitions apply if the transfer of money or anything of value is made to any person (rather than the foreign official directly) who will use the funds or thing of value to improperly influence or induce a foreign official
  - These acts are illegal if use mail or other means of international commerce or do any act in furtherance of the illegal scheme outside the US whether mail or other means of international commerce is used

Foreign Corrupt Practices Act

- Affirmative Defenses
  - Payment, gift, offer or promise of anything of value is lawful in the foreign official's country
  - Payment, gift, offer or promise was a reasonable and bona fide expenditure such as travel incurred by or on behalf of a foreign official directly related to promotion, demonstration or explanation of products or services or the execution or performance of a government contract
- Exception: facilitating or expediting routine government actions

Foreign Corrupt Practices Act

- Key terms:
  - "Foreign official" means any officer or employee of a foreign government or any department, agency or instrumentality or a public international organization or any person acting in an official capacity for or on behalf of such government or department, agency or instrumentality or public international organization
  - "Routine government actions" include obtaining permits, licenses, processing government papers, providing police protection and other government services such as mail delivery, phone, water and power, protecting perishable commodities

FCPA

- FCPA, Life Science Companies and Health Care Industry—Risk Areas
  - Biotech, pharma and device companies conduct clinical trials and/or take other action in support of marketing authorizations in other countries
    - Employed physicians and hospital executives of public hospitals where clinical trials are conducted may be “foreign officials.”

FCPA and Health Care

- FCPA and Life Science Companies—Risk Areas
  - Pharma, biotech and device companies market their products to hospitals and doctors
    - AGA Medical Corporation settlement of FCPA charges involving improper payments to Chinese physicians employed by government owned or controlled hospitals to buy AGA products
    - Syncor International Corp settled an action involving payments and other transfers to physicians in Mexico, Belgium, Taiwan, France to purchase their products

FCPA and Healthcare

- Risk Areas—payments to doctors, hospitals
  - Johnson & Johnson paid a fine of $70 Million in part for bribing doctors and hospitals in several European countries with national health systems to buy its products
    - For more examples of these prosecutions, see S. Korkor, N. Saleem, “Enforcement of Foreign Corrupt Practices Act in the Healthcare Industry and Foreign Bribery’s Adverse Consequences for Patients,” (2012)

Foreign Corrupt Practices Act

- Foreign Corrupt Practices Act and life science companies
  - Officials of agencies granting market authorizations for drugs and devices are foreign officials
  - Foreign agencies that must approve reimbursement for drugs or devices under a national health system are foreign officials
    - Pfizer settled FCPA charges admitting that it bribed foreign officials in Croatia, Russia, Bulgaria and Kazakhstan to secure regulatory approval and formulary approval for its products

FCPA and Healthcare

- FCPA and Life Science Companies—Risk Areas
  - Many of the transfers to doctors and other healthcare professionals were in the form of travel expenses to conferences, consulting contracts, personal loans, illegal commissions
  - Half of the FCPA enforcement action in healthcare involved payments to healthcare professionals (Korkor and Saleem (2012))

Other Applicable Law

- Other applicable US law
  - Travel Act prohibits use of a facility of foreign or interstate commerce to facilitate bribery
  - Restrictions on payments to healthcare professionals: e.g., Antikickback Statute and False Claims Act Statute
- Foreign Law—Healthcare Industry Specific
  - These laws may sharply limit marketing to consumers or healthcare professionals
- Foreign Law--Corporate Corruption
  - International conventions obligate signatories to take steps to effectively combat corruption (OECD, UN, Council of Europe, Inter-American Convention Against Corruption)
  - Many countries have passed tough laws—e.g., UK Anti-Bribery Act

Global Compliance Resources

- US Department of State: "Fighting Global Corruption: Business Risk Management"
- US Department of Justice: "A Resource Guide to the US Foreign Corrupt Practices Act" (2012)
  - Also—DOJ issues advisory opinions on whether a practice would violate the FCPA
- US Department of Commerce: "Business Ethics: A Manual for Managing a Responsible Business Enterprise in Emerging Market Economies"
- OECD Council, "Good Practice Guidance on Internal Controls, Ethics and Compliance" (2010)

Take-aways

- Strong compliance programs are critical
  - Reduces risk of a company engaging in improper conduct
  - If improper conduct occurs, government will take into account the existence of corporate compliance program in determining what enforcement action to pursue

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Key Considerations When Determining FMV Compensation for Health Care Professionals on a Global Basis

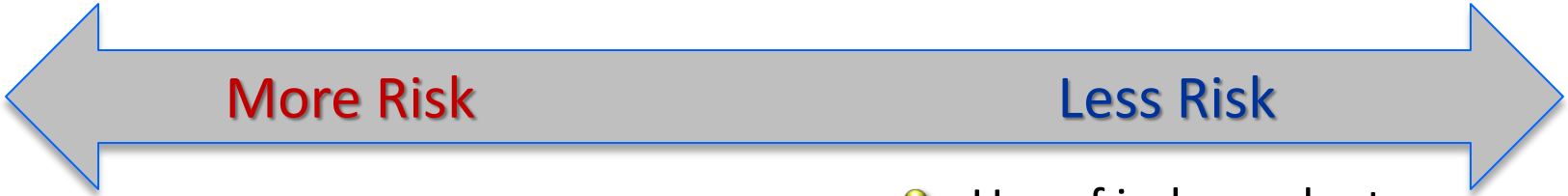
Presented By:

Ann S. Brandt, PhD, Partner | HealthCare Appraisers, Inc.

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”

- 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

Definition of FMV

- **International Glossary of Business Valuation Terms**

  The term "fair market value" is generally defined as the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.

- **Healthcare Definition (Generally consistent between CMS and Anti-Kick Back Statute)**

  The term "fair market value" is defined as the value in arm's-length transactions, consistent with the general market value. In the context of the Agreement, "general market value" means the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well informed parties to the agreement who are not otherwise in a position to generate business for the other party.

HCPs Versus KOLs

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.
- The HCP's CV is the typical source for information.
- 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)
- 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.

Securing Key Constituent "Buy-In"

- ***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…

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

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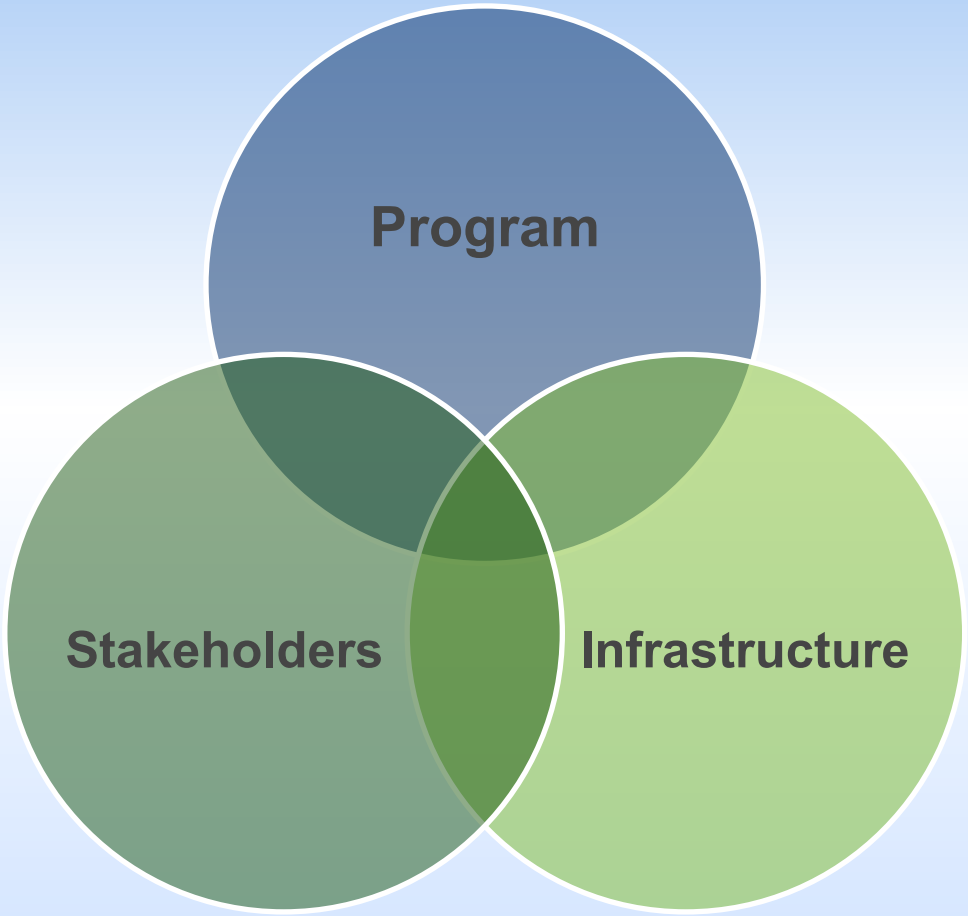
Drivers of Success



First things First … Valuation Battle Plan

Need to take inventory of:

What is the scope/goal of your FMV project?
- "Do I need the Cadillac or the Pinto?"

What resources do you have?

What resources do you need?

Getting Started- Enlisting the Right Support

Your Leadership team needs to be on board & support the project
- **Keep in mind that results may trigger a business impact**

Building a successful project team
- **Business transaction knowledge is essential**

Partnering Externally
- **Wealth of knowledge and best practices**

Program- Identifying your Universe

What Healthcare professionals do you interacting with?

What activities are the Healthcare professionals performing?

How do you select what Healthcare professional to engage with?

What types of attributes do you value in Healthcare professionals?

Stakeholders …. Engage, Engage, Engage

Who are my stakeholders?

- Anyone who will use the valuation tool or output

Identify your stakeholders early and engage them

- Marketing? Product Management? Research? ….. Sales?

Socialize the team to the WHY

- Why a FMV framework is necessary & what is in it for them

Empower your stakeholders to help with the input of the framework

- People are likely to accept something that reflects their input

Program - Guts & Complexity

How do you organize your universe of HCP's?

- **Look for Patterns**
- **Identify Categories**

Complexity will be determined by the amount of diversity

How do you assign value?

- **Stratification/Tiers**
- **# of Attributes**

The better you know your universe the easier this will be!

System

What is your infrastructure going to be?

- Fully integrated system, embedded drop down tool, excel file

<u>Considerations</u>

- **Funding**
- **IT Resources**
- **Controls**
- **Data Extracts**

Controls & Monitoring

Data Governance- Define ownership & ongoing management of the data to ensure accuracy, accessibility, completeness & updating

Exceptions- They will happen! Build a process to handle them upfront – escalation, approval, documentation

Monitoring- Back end monitoring critical to validate integrity of the program

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

Questions & Answers

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