

# Clinical Trial Agreements, Investigator Payments and FMV

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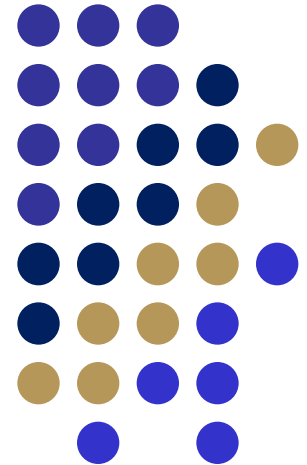
*with*

David Vulcano, LCSW, MBA, CIP, RAC, AVP Clinical Research | HCA, Inc.

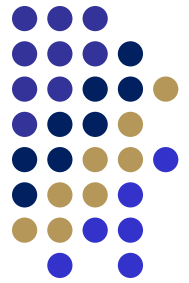
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***“Herding Cats and Chasing Unicorns:  
Implementing FMV in Clinical Research Budgets”***

December 7, 2016 | Philadelphia, PA



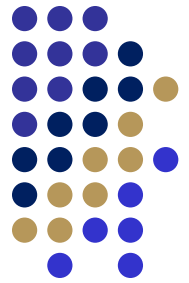
# Introductions and Disclosures



*Andrea Ferrari, JD, MPH | Director, HealthCare Appraisers, Inc. (HAI)*

- ❑ Trained and practiced as a corporate/healthcare regulatory and transactional lawyer
  - ❖ Formerly with global law firm representing various hospitals, health care businesses and life sciences companies in both domestic and international matters
  - ❖ Former associate counsel for a health system
  - ❖ Representation of clients in transactional matters and before regulatory agencies
- ❑ Started career as clinical research coordinator/consultant
- ❑ Frequently speaking, publishing and serving as an expert regarding fair market value for physician/healthcare provider services and why it matters for regulatory compliance and/or otherwise keeping out of trouble
  - ❖ KOLs/"Rockstar" physicians
  - ❖ FMV for clinical research budgeting
  - ❖ Defensibility of FMV opinions
  - ❖ FMV, ethics and risk mitigation in health care transactions
- ❑ Third term Chair, American Health Lawyers Association (AHLA) Fair Market Value Affinity Group
  - ❖ Hospitals and Health Systems Practice Group
  - ❖ Life Sciences Practice Group
  - ❖ Academic Medical Centers and Teaching Hospitals Practice Group

# Introductions and Disclosures

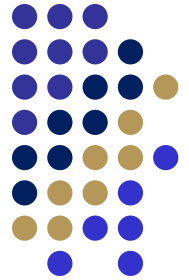


## About HAI

- ❑ Founded in 2000 to meet the regulatory mandate for FMV in relationships between health care referral sources (Stark Law, Antikickback Statute, Foreign Corrupt Practices Act)
- ❑ Exclusive focus is FMV and commercial reasonableness in the healthcare and life sciences industries
- ❑ Eight offices and growing
  - ❖ Florida (2 offices, corporate headquarters), Baton Rouge, Chicago, Dallas, Denver, Nashville, Philadelphia, San Francisco (coming soon)
  - ❖ Clients in all 50 states and beyond
  - ❖ Domestic and international services
- ❑ Many long-term clients for whom HAI has been a trusted advisor and performed thousands of valuation services and consulting engagements
- ❑ “I was a client before I was an employee.”
- ❑ An ESOP company
  - ❖ Portion of company ownership is held by employees in an Employee Stock Ownership Plan

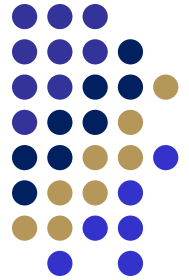


# Disclaimers



- ❑ This program is a general discussion of legal, business and valuation issues that may arise in the context of transaction planning and should not be relied upon as legal, valuation, business, financial, or other professional advice.
- ❑ Not all slides will be covered in detail. Some have been included for reference only.
- ❑ The slides and discussion may represent personal views and not necessarily those of current or past employers or clients.
- ❑ This presentation may include discussion of hypothetical scenarios. Hypothetical scenarios are devised to be illustrative. They are not a complete depiction of possible scenarios, and they may not be representative of actual circumstances in any particular study.

# Agenda

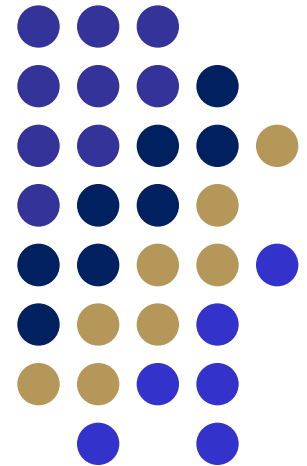


- ❑ Review of what “Fair Market Value” (FMV) means and why it is important for clinical research budgets (not necessarily in that order)
  
- ❑ Explore role of FMV in the clinical research budgeting and contracting process
  - ❖ Establishing budgets with Sponsors
  - ❖ Determining Investigator Payments (to and from)
  - ❖ Determining facility payments for support services and personnel
  
- ❑ Tips, pitfalls and illustrations of implementing FMV in the clinical research budgeting and contracting process

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*How Do You Define and  
Why Do You Care About FMV  
(and Commercial Reasonableness)*



# Why Care About FMV?



## Stark Law:

- Strict Liability
- High price tag for violations
- Liability for each claim submitted, unless an exception applies
- Multiple exceptions have commercial reasonableness and/or fair market value requirement

## Anti-kickback Statute:

- Criminal statute with provisions for civil monetary penalties
- Multiple voluntary safe harbors have fair market value and commercial reasonableness requirements
- Intent -based violations
- Multi-million dollar question: Will remuneration that is not fair market value and not commercially reasonable be viewed as evidence of illegal intent?

## Foreign Corrupt Practices Act:

- Makes it illegal to pay bribes to foreign officials (criminal penalties)
- Applies to U.S. citizens, nationals, residents, and corporations/businesses organized under the laws of the U.S. (including any state), or having a principal place of business in the U.S.
- Is a concern when conducting research in foreign countries with nationalized healthcare where providers or administrators are government agents

## Federal False Claims Act:

- *Qui tam* provisions = magnifying glass for Stark Law, Anti-Kickback violations
- Trebles damages for other violations
- Recent legal changes may have made it easier for relators to bring and pursue claims

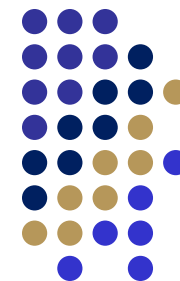
## IRC 501(c)(3):

- Applies to tax-exempt not-for-profit entities
- Compensation should be reasonable
- Costly penalties for failure to comply – intermediate sanctions, loss of tax-exempt status

***Compensation that is not FMV or otherwise does not seem reasonable might be used as evidence for allegation of an illegal payment***

**State counterparts to the above, and other state laws** - receiving more attention in recent whistleblower lawsuits and settlements, particularly with Medicaid expansion and the growing importance of state funding for healthcare

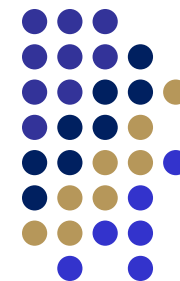
# Why Care About FMV?



- ❑ 1994: OIG “Special Fraud Alert” warns that compensation relationships between pharmaceutical manufacturers and physicians may implicate the AKS if compensation is more than nominal in value and exceeds the **FMV** of any legitimate service rendered to the payor by the physician
- ❑ 2003: OIG issues *Compliance Program Guidance for Pharmaceutical Manufacturers*: The concept of “**FMV**” is raised at least five times:
  - ❖ [with respect to payments to physicians for research] “Payments for research activities should be **fair market value** for legitimate, reasonable and necessary services.”
  - ❖ [with respect to contracts for data collection services] “These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be **fair market value** for legitimate, reasonable and necessary services.”
  - ❖ [with respect to items given to physicians] “If goods or services provided by the manufacturer eliminate the expense that a physician would have otherwise incurred... or if items are sold to a physician at less than their **fair market value** the arrangement may be problematic...”

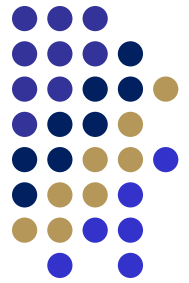


# Why Care About FMV?



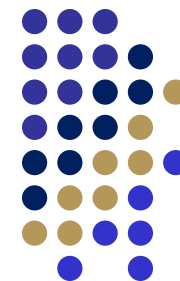
- ❑ 2003 OIG *Compliance Program Guidance for Pharmaceutical Manufacturers* [cont.]
  - ❖ [with respect to factors that should be considered when not complying with a safe harbor] “Do fees for services exceed the **fair market value** of any legitimate, reasonable and necessary services rendered by the physician to the manufacturer?”
  - ❖ [with respect to compensation relationships related directly or indirectly to a manufacturer’s marketing and sales activities] “At a minimum, manufacturers should ...review arrangements for physicians’ services to ensure that: (i) the arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at **fair market value**; and (v) all of the preceding facts are documented prior to payment.”

# Why Care About FMV?



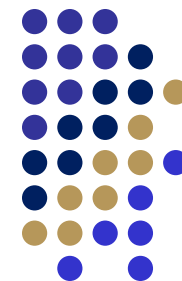
- ❑ 2005 OIG Supplemental Compliance Program Guidance for Hospitals advises caution about hospital-physician relationships are not **FMV**
  - ❖ *The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at **fair market value** for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the volume or value of any past or future referrals or other business generated between the parties.*
  - ❖ *Arrangements under which hospitals (1) **provide physicians with items or services for free or less than fair market value**, (2) **relieve physicians of financial obligations** they otherwise would incur, or (3) **inflate compensation paid to physicians for items or services** pose significant risk. In such circumstances, an inference arises that the remuneration may be in exchange for generating business.*

# Why Care About FMV?



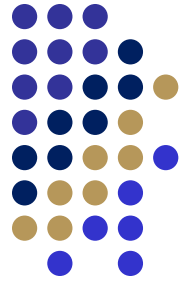
- ❑ 2013 implementation of Physician Payments Sunshine Act/open payments law
  - ❖ Intended to create transparency about payments flowing from Manufacturers to physicians and teaching hospitals
  - ❖ Transparency may make seemingly inappropriate payments easier for government enforcement entities to identify
  - ❖ Transparency raises the possibility of more vigorous government enforcement activity of the laws that are implicated by Manufacturer payments

# Why Care About FMV?



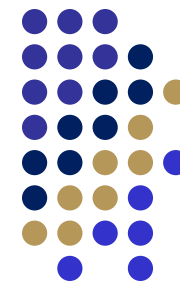
- ❑ 2014 OIG Special Fraud Alert re laboratory payments underscores that payments to providers to collect data (*e.g.*, for registry studies) may be suspect-
  - ❖ “OIG has become aware of arrangements under which clinical laboratories are providing remuneration to physicians to collect, process, and package patients’ specimens.”
  - ❖ “[C]laims that Registries are intended to promote and support clinical research and treatment are not sufficient to disprove unlawful intent... retaining an independent Institutional Review Board to develop study protocols and participation guidelines, will not protect a Registry Arrangement if one purpose of the arrangement is to induce or reward referrals.”
  - ❖ “The probability that a payment is [perceived to be] for an illegitimate purpose is increased...if a payment exceeds fair market value or if it is for a service for which the physician is paid by a third party, including Medicare.”

# Why Care About FMV?



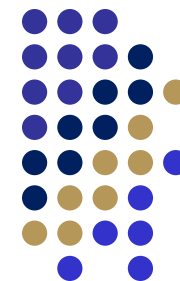
- ❑ 2015 OIG Special Fraud Alert re physician compensation arrangements warns that OIG may/will pursue civil, criminal or administrative action against physicians who enter inappropriate payment arrangements
  
- ❖ “Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business. OIG encourages physicians to carefully consider the terms and conditions of ...compensation arrangements before entering into them.”

# Why Care About FMV?



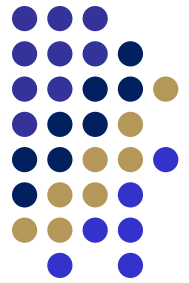
- ❑ Pharma/Med Device FCA/ anti-kickback settlements (incomplete list)
  - ❖ Pfizer (Warner-Lambert) - \$240 million (2004)
  - ❖ Schering-Plough - \$435 million (2005)
  - ❖ Lincare - \$10 million (2006)
  - ❖ Medtronic - \$40 million (2006)
  - ❖ Biovail Pharmaceuticals - \$22.2 million (2008)
  - ❖ Bayer HealthCare – \$97.5 million (2008)
  - ❖ Eli Lilly - \$1.4 billion (2009)
  - ❖ Pfizer - \$2.3 billion (2009)
  - ❖ Novartis - \$422.5 million & \$237.5 million (2010)
  - ❖ Merck KGaA - \$44 million (2011)
  - ❖ GlaxoSmithKline - \$3 billion (2012)
  - ❖ Abbott - \$1.5 billion (2012)/Pharmerica - \$9.25 million (2015)/Omnicare - \$28 million (2016)
  - ❖ J&J - \$2.2 billion (2013)
  - ❖ Abbott - \$5.48 million (2013)/Omnicare - \$28 million (2016)
  - ❖ Teva - \$27.6 million (2014)

# Why Care About FMV?



- ❑ Pharma/Med Device FCPA penalties/settlements (incomplete list)
  - ❖ J&J - \$70 million (2011)
  - ❖ Smith & Nephew - \$22 million (2012)
  - ❖ Pfizer - \$45 million (2012)
  - ❖ Eli Lilly - \$29 million (2012)
  - ❖ Koninklijke Phillips Electronics- \$4.5 million (2013)
  - ❖ Stryker - \$7.5 million (2013)
  - ❖ Bristol-Myers Squibb -\$14 million (2015)
  - ❖ Olympus - \$646 million (2016) (AKS *and* FCPA claims)
  - ❖ SciClone Pharmaceuticals - \$12 million (2016)
  - ❖ Novartis -\$25 million (2016)
  - ❖ GlaxoSmithKline -\$20 million (2016)
  - ❖ AstraZeneca - \$5.5 million (2016)
  - ❖ Teva - \$520 million (2016)

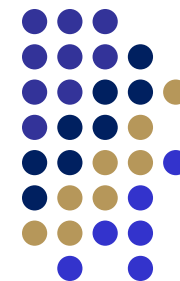
# Why Care About FMV?



- ❑ Hospital/Health System False Claims Act/Stark/Antikickback settlements to resolve allegations related to improper physician compensation (amounts do not include associated legal fees but do include amounts owed to states in addition to Federal liabilities) (not a complete list)
  - ❖ Covenant Medical Center - \$4.5 million (2009)
  - ❖ Bradford Regional Medical Center – hospital \$2.75 million (2011), physicians (\$500,000) (2014)
  - ❖ All Children’s Hospital - \$7 million (2014)
  - ❖ Halifax Hospital Medical Center – \$ 1 billion in potential damages and penalties, settled to \$85 million (2014)
  - ❖ King’s Daughter’s Medical Center - \$41 million (2014)
  - ❖ Citizens Medical Center – hospital \$21.75 million , physician \$400,000 (2015)
  - ❖ Columbus Regional Medical Center - \$35 million (2015)
  - ❖ North Broward Hospital District -\$69.5 million (2015)
  - ❖ Adventist Health System - \$115 million (2015)
  - ❖ Tuomey Healthcare System – 2 trials; hospital: \$237 million verdict settled to \$72 million (2005-2015); hospital executive: \$1 million (2016)
  - ❖ Lexington County Health Services District - \$17 million (2016)
  - ❖ Tenet Healthcare - \$514 million (2016)



# Why Care About FMV?



## ❏ Other Reasons to Consider FMV

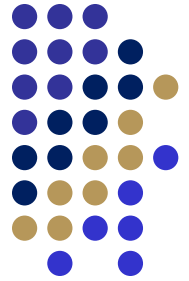
### ❖ PhRMA Code

- Compensation or reimbursement to physicians should be “reasonable and based on **fair market value**”
- Compliance with PhRMA code is voluntary in most instances, but required under the laws of certain states and local jurisdictions (MA, CA, NV, DC)
- Compliance with PhRMA code may be required to do business with certain larger and prestigious hospitals and academic institutions that have recently stringent rules for Manufacturer payments

### ❖ AdvaMed Code

- Compensation to physicians should be “consistent with **fair market value** in an arm’s length transaction for the services provided and should not be based on the volume or value of... past, present or anticipated business.”
  - Compliance with AdvaMed Code is voluntary but may be necessary to do business with entities that have recently adopted stringent rules for Manufacturer payments
- ❖ Compliance with AdvaMed Code or PhRMA code may be evidence of good faith in any AKS, FCA investigation

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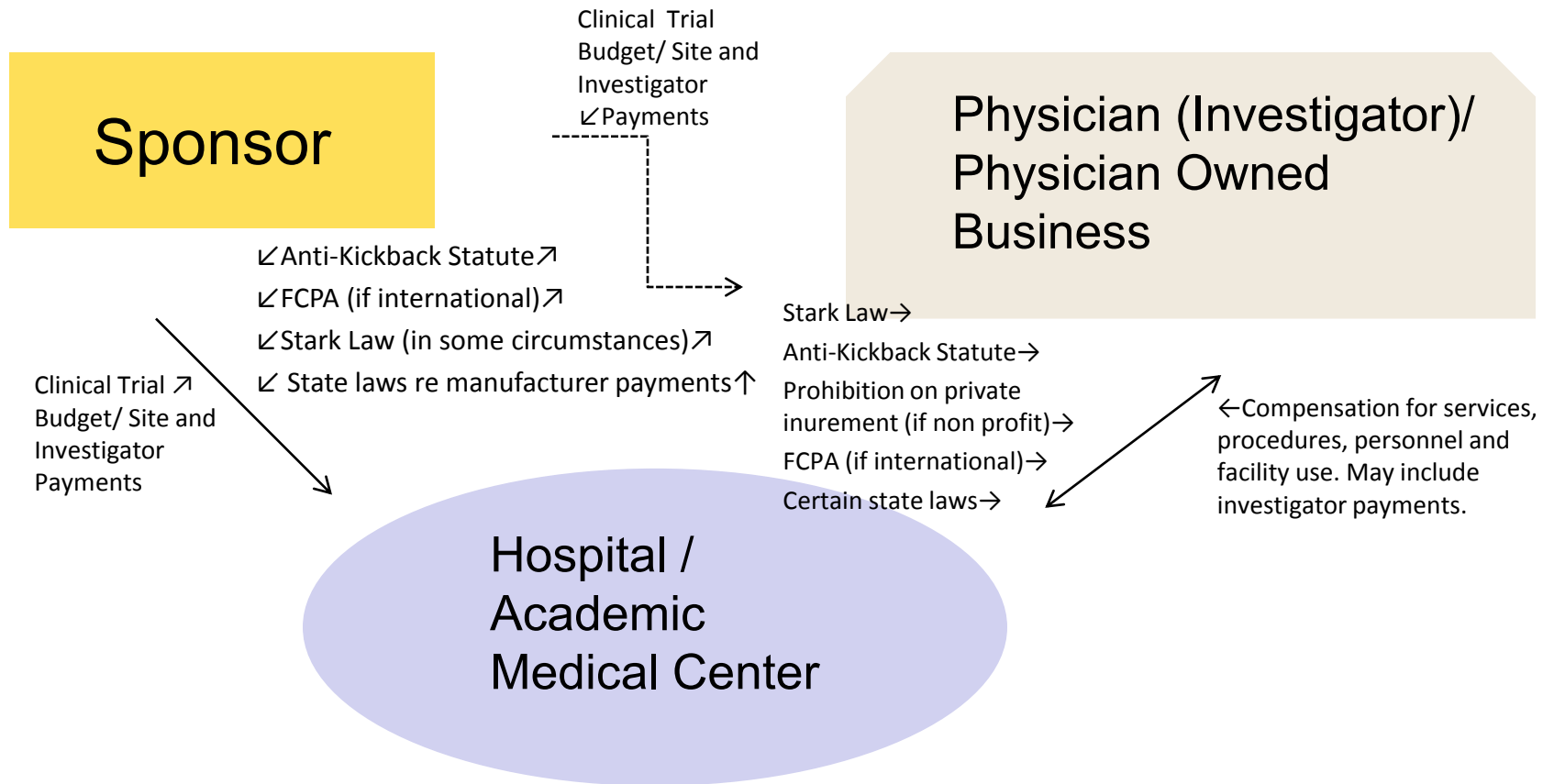
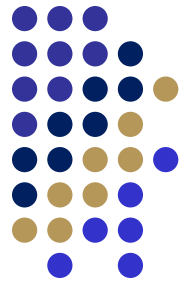


## □ Other Reasons to Care About FMV

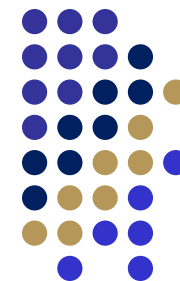
### ❖ Select State Law Issues

- State anti-kickback statutes
- State Stark laws
- Fee splitting
- Physician payment disclosure requirements
- Fiduciary issues

# Why Care About FMV?



# What Does “FMV” Mean?

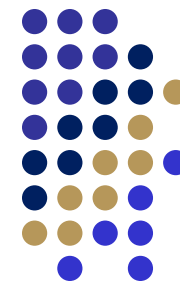


- ❑ **Stark Law (a “strict liability” statute) has a specific definition in the text of the statute and its promulgating regulations**

**Statute: (42 USC § 1395NN(h)(3))-** *“fair market value” means the value in arm’s length transactions, consistent with the general market value...*

**Regulations: (42 CFR §411.351) –** *“General market value” means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or 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, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.*

# What Does “FMV” Mean?

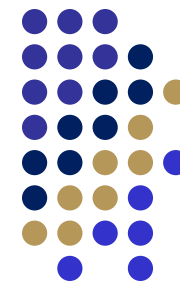


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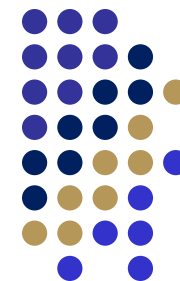
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# What Does “FMV” Mean?



- ❑ The Stark Law definition of FMV is augmented by various regulatory guidance that suggest how it may be determined
  - ❑ Stark Phase I Preamble (66 Fed. Reg. 944) - FMV may be established “by any method that is commercially reasonable that provides evidence that compensation is comparable to what is ordinarily paid for the item or service in the location at issue, by parties in arm’s length transactions who are not in a position to refer to one another.”
  - ❑ Stark Phase III (72 Fed. Reg. 51015)
    - ❑ “Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluation fair market value.”
    - ❑ “...the appropriate method for determining fair market value for the purposes of [Stark] will depend on the nature of the transaction, its location, and other factors...although good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party’s intent, it does not establish the ultimate issue of the accuracy of the value itself...”
  - ❑ **Summary (IMO):** There are many reasonable methods to determine FMV, but one needs to select and implement the methods carefully, as not every one will lead to an accurate and defensible FMV determination for Stark Law purposes

# What Does “FMV” Mean?

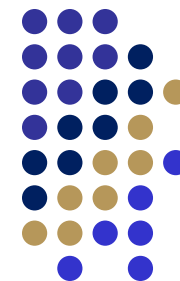


❑ **Anti-Kickback Statute: No explicit definition of FMV in the law, but many OIG publications are informative of how the government may informally define fair market value for AKS purposes**

- ❖ Guidance suggests a similar definition to the Stark law definition – i.e. fair market value is:
  - ❖ The value in arm’s length transaction
  - ❖ In a specific location and time
  - ❖ Where parties are informed and not under compulsion to buy or sell and
  - ❖ There is no tainting by the potential of the parties to the transaction to generate referrals or other business for each other

❑ **FCPA/IRS Definition?**

# What Does “FMV” Mean?

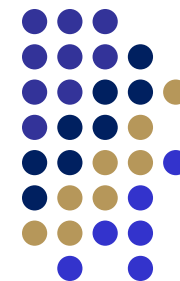


## □ Government commentary, advisory opinions and case law suggest FMV is probably not:

- ❖ The amount that results from earnest negotiations
  - earnest is not necessarily “arm’s length” when there are potential business referrals in play
- ❖ The amount that a specific party “normally charges” for services
- ❖ Opportunity cost
- ❖ What a party paid or received for similar services from another party last year (unless certain conditions apply)



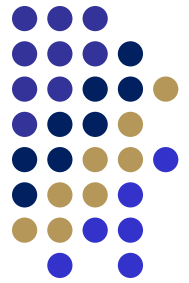
# What Does “FMV” Mean?



## □ Government commentary, advisory opinions and case law suggest FMV probably is:

- ❖ A value or range of values that results from commonly accepted valuation principles and/or from otherwise reasonable processes and data that establish what compensation *would be* in a transaction that is similar, but in which parties are not in a position to refer or otherwise generate additional business for each other
- ❖ A hypothetical concept – i.e. not necessarily what specific parties to a specific transaction think that the subject items or services are worth
- ❖ A value that changes as market forces and circumstances change
  - FMV today may be different than FMV 5 years ago, 3 years ago or 2 years ago
  - FMV today may be more or less, or may be based on different prevailing payment methods, than 5 years ago, 3 years ago or 2 years ago
    - Some market evidence that hourly rates paid by pharma are declining

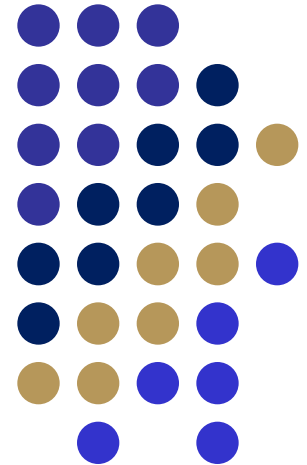
# Don't Forget About “Commercial Reasonableness”



- ❑ **Multiple Stark Law exceptions and Anti-kickback safe harbors have a requirement that compensation arrangements be “commercially reasonable” in addition to FMV**
  - ❖ **There is no statutory definition of “commercially reasonable,” but there is government guidance that courts have found persuasive:**
    - ❑ **1998 Stark Proposed Rule**
      - ❑ *An arrangement is commercially reasonable if it “appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.” (63 Fed. Reg., 1659, 1700 (Jan. 9, 1998))*
    - ❑ **2004 Preamble to Stark Phase II Interim Final Rule (in response to a comment)**
      - ❑ *“An arrangement will be considered commercially reasonable in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.” (69 Fed. Reg. 16054 (March 26, 2004))*

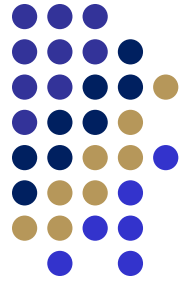
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***FMV in Clinical Research Budgeting  
Illustrations, Tips and Pitfalls***



# FMV in Clinical Research

## Budgeting/Contracting



### □ Examples of Common Clinical Trial Needs

- ❖ Investigator(s) to oversee clinical trial
- ❖ Physician professional services that are not investigator services but are required to comply with the protocol – *e.g.*, cardiology consult that is needed to determine if the subject in an oncology trial meets inclusion/exclusion criteria and/or should be removed from the protocol due to adverse effects
- ❖ Technical services or globally packaged services/procedures that are needed to comply with a protocol - *e.g.*, specific lab tests, radiology tests
- ❖ Services of clinical research support personnel such as study coordinator, research/dispensing pharmacist, biostatistician, etc.
- ❖ Facilities and space use
- ❖ IRB review and monitoring, which typically incurs fees
- ❖ Study-specific items or services – *e.g.*, nebulizer to deliver study medication, dedicated centrifuge to process study samples

# FMV in Clinical Research Budgeting/Contracting

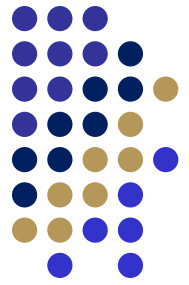


## ❑ Money Flow Determines FMV Risk Areas



- ❖ Investigator Services
- ❖ Physician Professional Services
- ❖ Technical/Procedure/Packaged Services
- ❖ Clinical Research Support Services (Study Coordinator, Pharmacist, Biostatistician, etc.)
- ❖ Facilities and Space
- ❖ Study Specific Items
  - Each item may be provided by a different party
  - Each should be paid at FMV under a commercially reasonable arrangement to mitigate liability risk
  - The game of “Give here and take there” should be undertaken cautiously, it at all

# FMV in Clinical Research Budgeting/Contracting



## □ David Vulcano's Cartoon:

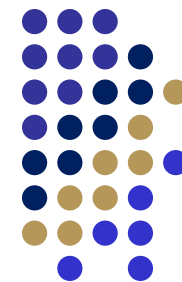
I can't go over \$110 for Inclusion/Exclusion verification because you will be outside of FMV but I can give you another \$15 on the Informed Consent line item.

Ok, at least the total per visit is the same.

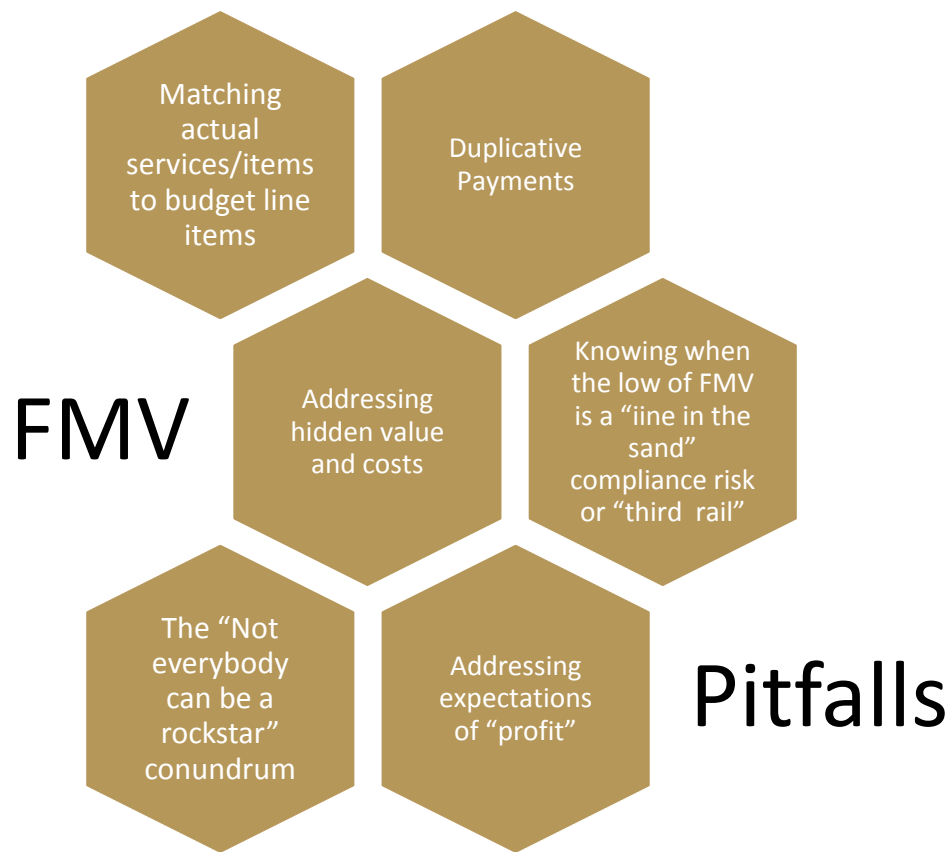


# FMV in Clinical Research

## Budgeting/Contracting – Tips, Pitfalls

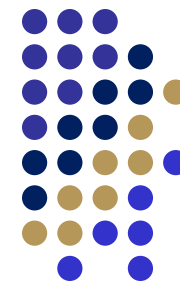


### □ FMV trouble spots in clinical research budgeting



# FMV in Clinical Research

## Budgeting/Contracting – Tips/Pitfalls



### □ FMV trouble spots in clinical research budgeting

Matching  
actual  
services/items  
to budget line  
items

Duplicative  
Payments

*E.g.*, What is entailed in “informed consent” or “start up”?

- Is it exactly the same of every trial/study?
- Be sure you are comparing “apples to apples”
- Key questions: Who does what? How long does it take? What resources are involved
- De-bundle services and convert them to personnel time (hourly rates) and fixed value components

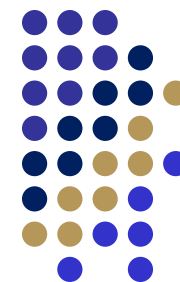
1<sup>st</sup> rule of FMV: Thou shalt not duplicate payments

- Some physician professional services and technical services are billable to Medicare or other health care payors
- The amount paid by those payors are payment in full for the services that corresponds to the relevant billing code = to avoid an FMV pitfall, only the FMV of *incremental* services that are not covered by the billed code should be paid by the site/sponsor contract
- Services by employed physicians may be subject to compensation through pre-determined/contractually fixed compensation rates per wRVU. Do not pay or accept compensation for physician services without taking this into account



# FMV in Clinical Research

## Budgeting/Contracting – Tips/Pitfalls



### □ FMV trouble spots in clinical research budgeting

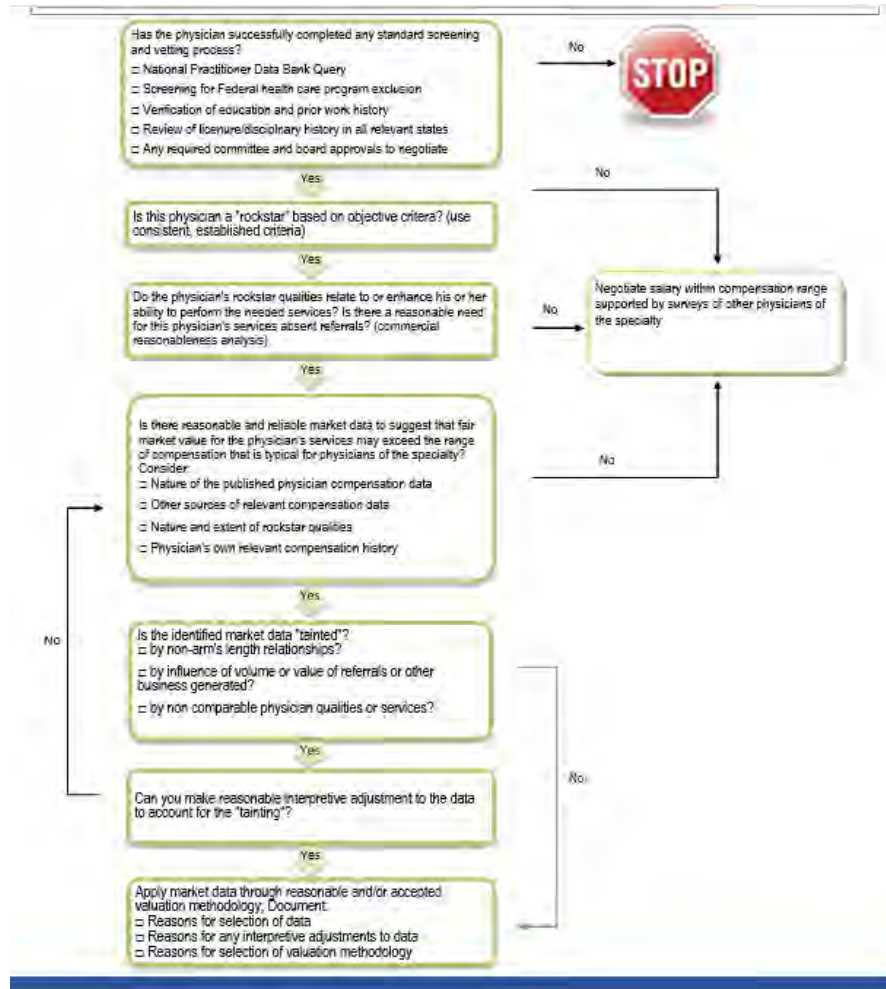
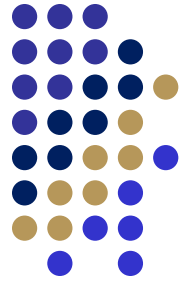
Knowing when the low of FMV is a “line in the sand” compliance risk or “third rail”

Addressing hidden value and costs

- If a hospital is providing items or services to an Investigator or other physician party in connection with the study, the amount charged for those services should not be below FMV (this is a compliance issue) = FMV is a line in the sand
- Medicare rates are generally FMV, but they are on the low end of the FMV range
  - Medicare rates may be ok if used uniformly for all services in a study budget (since they are FMV) but
  - Depending on circumstances, there may be a commercial reasonableness issue if services are flowing between parties and physician receives comp that is 3X Medicare while hospital receives Medicare rates only

- E.g.*, Clinical research support services are provided by individuals who are not reasonably dedicated full time to the study
- Depending on the nature of the study, certain individuals (coordinator, pharmacist, etc.) may be needed only part time or sporadically; services may be needed immediately “on demand” when a patient-subject is identified and enrolled, but it is unknown when or how often patient-subjects will be identified
  - Part time, on demand services are a premium in the marketplace (consider hourly cost of locums or temps versus full time exclusively dedicated employees)

# FMV in Clinical Research Budgeting/Contracting – Tips/Pitfalls

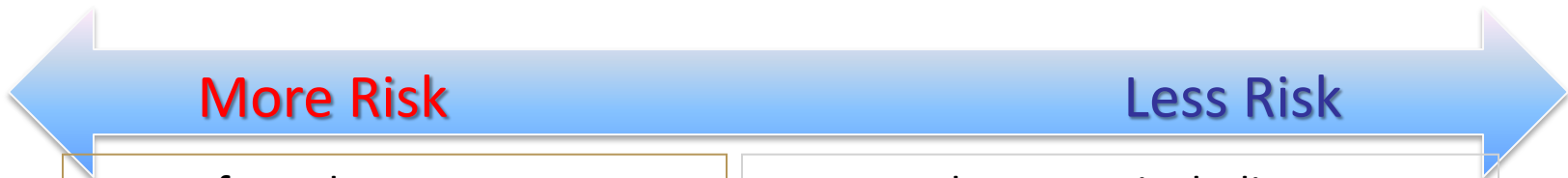
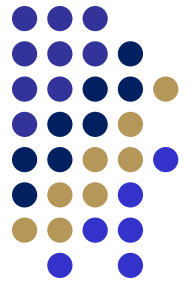


## Sample Anatomy of a Physician Rockstar Analysis

# FMV in Clinical Research

## Budgeting/Contracting – Tips/Pitfalls

### □ FMV trouble spots in clinical research budgeting



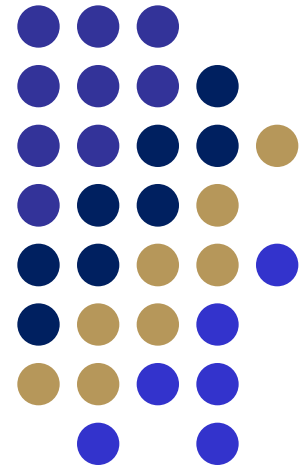
- No formal process
- Payments based upon:
  - Physician “demands”
  - What “seems” right

- Formal process, including documentation
- Use of an appropriately qualified, experienced, independent valuator
- Use of accepted valuation approaches
- Selection and application of market data is documented to show a reasonable, logical, defensible conclusion of value

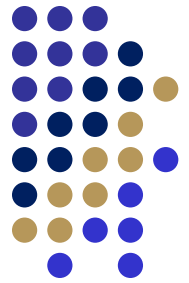
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*Putting it All Together –  
What Can You Do to Herd Those Cats?*



# Recommendations/Options



## □ FMV Budgeting Toolkit

- ❖ Update at least every two years to account for market changes
- ❖ Toolkit may include:
  - Summary and/or access to FMV ranges for hourly or other applicable per-service or per-item rates for services most commonly needed in connection with the facility's clinical trials/clinical research
  - General guidance on how to apply the FMV ranges in the tool, including:
    - Deconstructing a budget to match budget line items to actual items/costs
    - Caveats to applying the FMV hourly or other applicable service rates to certain specific circumstances
    - Triggers for higher or more specific level of review than can be accomplished through the general toolkit (case specific legal review, FMV review) – may include:
      - Questions about potentially duplicative payments
      - Non-typical or hidden value and costs
      - Concerns about payments at the low of FMV
      - Unique services or service providers, such as but not limit to, as Rockstar investigators

# Questions?

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