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FAIR MARKET VALUE AND CLINICAL TRIAL BUDGETS

Goals for the Session

- Fair Market Value means what to whom?
- Budgeting clinical trials can be difficult without knowing budget numbers from independent physician practices who do research with their facility
- How does this fit into compliance?

Definition?

- "The fair market value is the price at which the property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts."

  United States Supreme Court decision in *United States v. Cartwright*

According to a Glossary of Terms

- The price, expressed in terms of cash equivalents, at which a property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms' length in an open and unrestricted market, when neither is under compulsion to buy nor sell, and when both have a reasonable knowledge of relevant facts.

Fair Market Value

- Payment set at what the market will bear that is in accordance with being able to defend the payment
- Most facilities now have a FMV policy in writing to defend their actions and to prove transparency

Factors that Affect Assessment of FMV

- Federal Anti-Kickback Statute
- False Claims Act
- Food, Drug and Cosmetic Act

Checklist for Determining FMV

- Physician's "going rate" does not necessarily constitute FMV
- Historical compensation does not necessarily constitute FMV
- Opportunity costs should no be relied on to determine FMV
- Administrative services value may differ from clinical services

FMV

- Should be defensible and documented
- Demonstrate a consistent methodology
- Be transparent

Not a Cookie Cutter Proposition

- Negotiated budgets
- No "perfect solution" to the FMV dilemma
- Determined by the players
- Some sites have set rates

Speaking from a Sponsor's Point of View

- Use data bases to decide what to pay sites
- Use 50th percentile which is the data point at which 50% of the values are less than or equal to that data point
- It's Monopoly Money!
  - Since every budget is negotiated, *EVERY* data point represents the FMV for that data point
- If a database of studies contains the information for 100 individual contracts, the 50th percentile would represent the point at which 50 sites negotiated a lower or equal rate, and 50 sites negotiated a HIGHER rate

The Bottom Line

What other sites negotiate affects your site!

Data Bases are Used Inconsistently

- Not real time data
- Data does not take into account enrollment success or quality of work performed
  - Data includes the "negotiated" budgets for all sites that signed a Clinical Trial Agreement, regardless of whether the site enrolled a single subject and whether the site "knew" what they were doing
- High performing sites do not benefit from data base use because it has too narrow a range from less experienced sites

A Properly Negotiated Clinical Trial Budget is Making Certain That Your Site Is

- Reimbursed for all direct costs of conducting the study
  - Must do a coverage analysis to ensure you know the costs
- Recovering an equitable amount of indirect study costs and administrative costs
- Earning a return on investment that is enough to stay competitive
- Ensuring that you do not have to reduce staff or resources
- Managing risks well to ensure that the site is not in jeopardy

What Are the Costs Associated With A Study?

- Indirect
- Direct
- Opportunity
- Overhead
- Start Up
- Hidden or Secret

Indirect Costs

- Costs of Non-visit related study start-up and close out
- Occupancy (rent, power, security, beepers, etc.)
- Accounting & legal fees
- Study/Business development
- Cost of industry conferences (fees, airfare, etc.)
- Insurance – general & research specific
- IT (phones, computers, internet access, website, etc.)
- Office supplies
- Medical records
- Biologic/sharps waste disposal
- Human Resources
- Internal accounting (including billing & reconciliation of study receivables and collections)
- Depreciation
- Other/Miscellaneous
- Surprise costs

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Direct Costs

- Costs incurred specifically related to conducting a particular study at your site
- You MUST perform a carefully scrutinized budget to know the direct costs
- Do a coverage analysis to know all patient care costs

Opportunity Costs

- The required return on the assets utilized to conduct the study that might otherwise be invested in some other activity or pursuit that could generate a return on those assets to the company
- What could you be doing if not this study?
- Examples: lab shipping that are in excess

Overhead

- Administrative Costs
- Stay in Business Cost

Start Up

- Administrative
- IRB and Regulatory Cost
- Budget and Contract
- Coverage Analysis
- PI Cost

Hidden or Secret Costs

- Delayed study start-up
- Delayed IRB approval
- Time to review and implement changes due to amendments
- Pre-screening activities not otherwise compensated
- Screen failures higher than expected
- Lower than expected enrollment
- High early termination or dropout rates
- Unscheduled visits
- Uncompensated monitoring visits or changes in monitors
- Time involved in supporting remote monitoring
- Higher than expected number of safety reports
- Additional sponsor or CRO requests
- Preparation for and involvement in Audits
- Travel time (Investigator meetings, off-site subject visits, etc.)
- Other costs and time that are not specifically compensated for in the per subject compensation
- Data clean up

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Clinical Trials Management is a Business!

- The return on investment is the difference between long-term viability and failure!
- Do you know you true cost and what the FMV truly is?
- Number of sites who have filed bankruptcy this past year
- Will your site be next?

What is a Coverage Analysis?

- A clinical trial coverage analysis is a document that identifies and analyzes who the appropriate payer (i.e. the Sponsor, Medicare or other third party payor) is for each item and service required by a clinical trial as stated in the protocol and schedule of events.

The Best Defense in FMV in Clinical Trials

- Have consistent and transparent written policies
- Create a defensible thorough budget analysis for each study (Do not back in to the budgets)
- Apply a consistent approach to determining costs including a coverage analysis
- Document that there are legitimate reasons for compensating costs across a broad range of determinable values

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Create a Defensible Thorough Budget Analysis for Each Study

- Coverage Analysis
- Staff Time and Effort Calculation
- Study Task Time and Cost Estimates
- Determine Start-up and Close-out Costs
- Analyze Overhead Costs and Trend
- Determine return on investment to perform study
- Do not be afraid to turn down studies!

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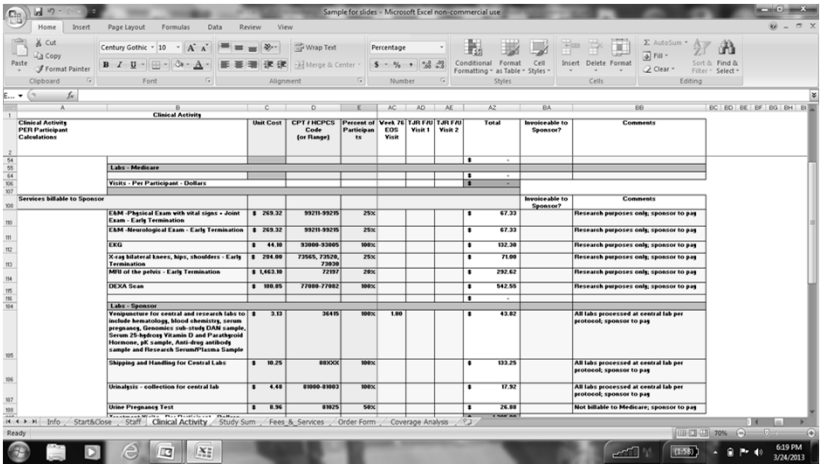
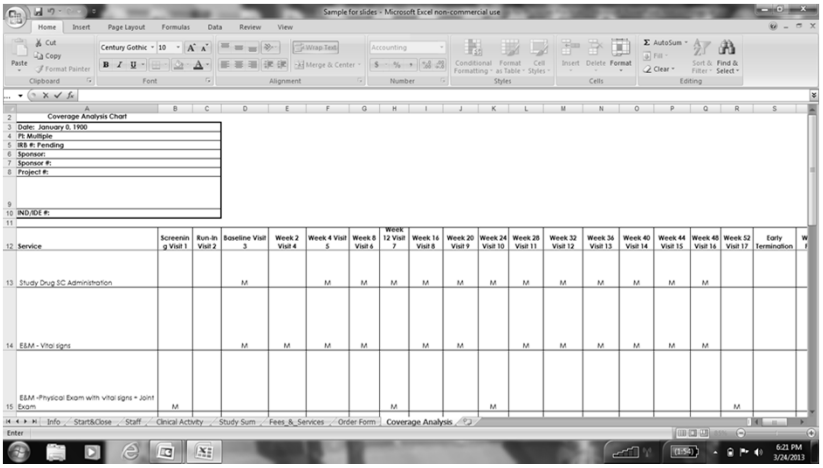
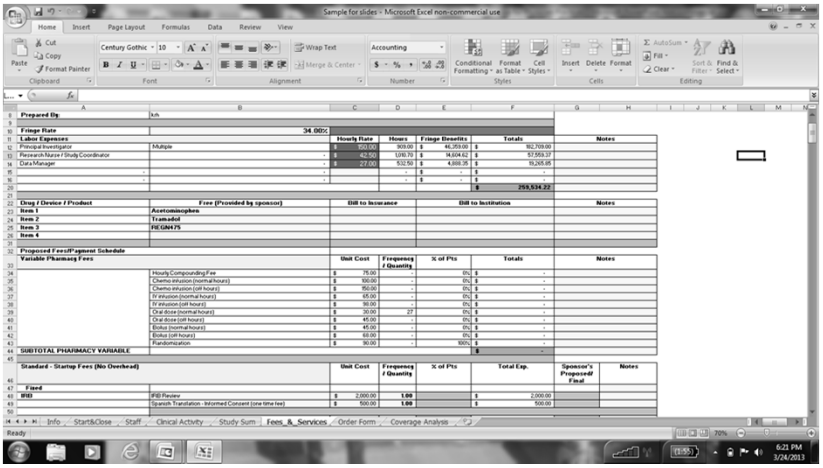
Example of Staff Time



Example of Coverage Analysis



Budget



Study Start-up & Close-out Costs

- Protocol Development
- Protocol submission
- Feasibility questionnaire development
- Confidentiality Agreement review and negotiation
- Pre Site Selection Visit
- Budget development and negotiation
- CTA development
- Indemnification Agreement development
- Drug Administration plan
- Investigator meeting Document development
- IRB document development and submission
- IRB follow up
- In-service of research team
- Subject packet preparation
- Site Initiation meeting

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Importance of Budget Information

- Budgeting clinical trials can be difficult without knowing budget numbers from independent physician practices who do research with your facility
- How do you handle the misconception that budget information is proprietary

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Importance of Budget Documents

Convergence of all of the protocol documents is critical to meet billing compliance guidelines

By not having budgetary line item documentation, you will not know what is "paid for" by the Sponsor

Physician practices can be held accountable if they *cause* to be presented, a false or fraudulent claim for payment or approval

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Benefits of a Coverage Analysis

- Sponsor is paying for items and services that can legitimately be billed under existing billing rules
- Both Sponsor and site can get a better understanding of what items and services are billable to Medicare and other third party payers
- If Sponsor performs a coverage analysis it will create efficiencies in budget negotiations and clinical trial implementation
- Ensures that items and services provided under a clinical trial are efficiently, effectively and compliantly billed to Medicare and other third party payors
- Provides a useful tool to justify payments to physicians and institutions for purposes of reporting under the Sunshine Act

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Fair Market Value

- The bottom line:
  - Support for the final indication of compensation should be well documented and defensible
  - Demonstrate a consistent and logical methodology when determining financial support for clinical trials

Questions and Discussion

Contact

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