PI Compensation: Methods, Documentation, and Execution

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This presentation has been developed for educational purposes only and does not constitute legal advice. It does not look at any unique circumstances in your particular organization.

Agenda

- Overview
- Legal & Regulatory Considerations
- PI Compensation Models
  - Model description
  - Budget and systems development for execution
- Other Considerations, Wrap-Up, Q&A

Overview

A frequent question asked in our industry is:

How much should we pay investigators for their work on a clinical trial, and what methodology should be used?

The amount and the method by which you use to pay investigators can play a big role in the success, or lack thereof, of your site.

Overview

The amounts paid to investigators are considered part of their overall compensation amount, and are thus subject to Fair Market Value (FMV) guidelines.

A firm understanding of the laws governing investigator compensation is key when determining amounts and methodology for payments to ensure compliance.

PART 1:
Legal & Regulatory Considerations

American Medical Association Opinion

AMA Opinion 8.0315 - Managing Conflicts of Interest in the Conduct of Clinical Trials Part 4

Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements

AMA AMERICAN MEDICAL ASSOCIATION

Legal and Regulatory Considerations

Three Important Components

1. Fair Market Value
2. Stark Law
3. Anti-Kickback Statute

Fair Market Value

The Centers for Medicare and Medicaid Services (CMS) defines FMV as:

"The value in arm's-length transactions, consistent with the general market value. '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…Usually, the fair market value 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…"

(42 CFR 411.351)

Fair Market Value

- In summary, compensation should not be in excess of **current market conditions** so as to not give the appearance that it would influence the decision of the investigator to participate in the trial, or to influence the outcome of the trial.
- If a PI is paid below FMV, it may prove to be a disincentive to participate, or enroll subjects, thus affecting your sponsor relationships and investigator relationships.
- If a PI is paid above FMV, **the institution is at risk from regulatory agencies**.

Stark Law

- The Physician Self Referral Law is also known as the **Stark Law**
- It is found in Section 1877 of the Social Security Act

Stark Law

The Law:

1. Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
2. Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
3. Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Stark Law

Where the issue arises for research institutions:

Payments made to the principal investigator become a financial arrangement (compensation) by and between the institution and the physician. Then if the physician refers subjects or other patients to the institution who receive reimbursement under Medicare or Medicaid, they could be in violation of the Law. Compensation for clinical trials need to be structured to fall within the Stark Law's exception for personal service arrangements (42 C.F.R. § 411.357(d)).

Stark Law Exception

In order to comply with this exception, personal service arrangements need to meet a number of requirements. *Here are some important selections:*

- The arrangement must be set out in writing, be signed by the parties, and specify the services covered;
- The arrangement must cover all services to be furnished by the physician to the entity, or incorporate by reference other arrangements or a master list of contracts; and
- The compensation paid over the term of each arrangement must be set in advance, must not exceed **fair market value**, and except in the case of a physician incentive plan, must not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

Stark Law Considerations

- This exception codifies the need for the institution to assess the fair market value of the principal investigator's services provided during the clinical trial in order to make certain that the compensation made to the principal investigator does not exceed fair market value.
- The arrangement between the institution and physician should be documented in a principal investigator payment agreement. This document should list the specific services that will be provided by the physician as principal investigator, as well as memorializing compensation amounts clearly.

Stark Law Penalties

Penalties for violations of the Stark Law include:

- Denial of payment for the Designated Health Service provided
- Refund of monies received by physicians and facilities for amounts collected
- Payment of civil penalties of up to $15,000 for each service that a person "knows or should know" was provided in violation of the law
- Three times the amount of improper payment the entity received from the Medicare program
- Exclusion from the Medicare program and/or state healthcare programs including Medicaid
- Payment of civil penalties for attempting to circumvent the law of up to $100,000 for each circumvention scheme

Anti-Kickback Statute (AKS)

The Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) is a criminal statute that prohibits knowing and willful conduct involving the solicitation, receipt, offer or payment of any kind of remuneration in return for referring, directly or indirectly, in return for either referrals of Medicare or Medicaid beneficiaries or the arranging, recommending, leasing or ordering of any item or service reimbursed by Medicare or Medicaid.

Anti-Kickback Statute (AKS)

The Anti-Kickback Statute also includes "safe harbor" regulations that describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. This includes a safe harbor for personal services contracts.

The personal services safe harbor contains several similar requirements as the Stark Law's exception for personal service arrangements. This includes that the arrangement must be set out in a writing and signed by the parties and that the payment constitute fair market value for the services rendered.

Anti-Kickback Statute (AKS)

Two key items to consider that are contained in the safe harbor include:

1. If the agreement is for less than full-time services, it must specify the schedule of such intervals, their precise length, and the exact charge for such intervals.
2. The term of the agreement must be for one year or longer. Or if modified/terminated at less than one year, may not be reinstated except at same financial terms. (e.g. Can not "renegotiate" until 12 months have passed.)

AKS Penalties

Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs. Under the Criminal Monetary Penalties Law, physicians who pay or accept kickbacks also face penalties of up to $50,000 per kickback plus three times the amount of the remuneration

Important Point to Remember

"**Fair Market Value**" and "**Commercial Reasonableness**" are important concepts in both Stark exceptions and Anti-Kickback Statute Safe Harbors

PART 2:
PI Compensation Models

PI Compensation Models

There are three popular models for paying principal investigators:

1. Research Salary
2. Percentage of Study Budget
3. Hourly rate for work performed

Research Salary

Description – In this method, the PI is paid a fixed salary for all their time spent working on clinical trials.

Pros – You always know your expense amount and the PI always knows the amount they will be paid. Less time with administrative tracking.

Cons – Can be risky if volume falls. This method could prove very costly on a per hour analysis and could be construed as receiving compensation above FMV as it relates to Stark and AKS. On the other hand, if volume rises, the PI may feel they are not being compensated enough.

Research Salary: Operational Logistics

- Strategy does not align with standard sponsor budgeting formats
- Goal = Be able to show that salary is consistent with FMV hourly rates
- Time tracking to calculate actual payments to the PI is not needed, BUT…
- Time should be tracked…
  - To prove FMV compliance
  - To determine WHAT the actual salary should be
- No requirements for payment triggers attached to patient study activity

Calculating Salaries

Q: How do I calculate the research salary?

A: **FMV $ amounts/hour** *(based on PI's specialty, experience, location, etc.)* **x Anticipated research hours/pay period** *(estimate based on previous tracking and scope of new endeavors)*= **Salary per pay period**

Q: How do I calculate the hourly rate to ask from Sponsor if I know the salary?

A: Negotiate sponsor budgets using FMV $ amounts per hour understanding that what is paid out to the PI may not exactly match what is shown in the sponsor budget

Percentage of Study Budget

Description – In this method, the PI is paid a fixed percentage of the final study budget for all their time spent working on the specific clinical trial.

Pros – You share the risk with the PI. You have a fixed PI expensive percentage. Less time with administrative tracking.

Cons – Can be risky based upon the amount of time PI works on the trial vs. the actual dollars compensated and could be construed as receiving compensation above FMV as it relates to Stark and AKS.

Also becomes difficult to administer if Sub-Investigators are involved in the trial, or if there is a change in PI during the trial. Oftentimes expenses are front-loaded in a clinical trial, and the original PI will have been paid the lion's share of the compensation available due to early visits.

Percentage of Budget: Operational Logistics

Key questions to consider:

1. % of full per patient budget (i.e. every item)

OR % of portion (usually non-cpt related; time and effort items)

1. When is the PI paid?
   - Visit/CRF completion, Time of Sponsor Payment, End of Study?
2. Are % reimbursement of administrative fees also considered and honored?

Percentage of Budget: Operational Logistics

Ensuring cost coverage:

- Internal budget – Add PI % amount on TOP of the calculated bottom line.
- Consider pulling out expensive procedures that don't involve PI time into invoiceables
- Negotiate sponsor budgets using FMV $ amounts per hour
- Hour multipliers may be used in the sponsor budget in order to meet PI fee requirements from the internal budget

Talking to PI's About Study Budgets

- ***Does your Institution allow/ask PI's to review study budgets? Has this presented problems? If so, what problems?***

Hourly Rate for Work Performed

This method can be broken down into two unique methods based upon how you track the PI time. In both, you must assure that the hourly rate is within established FMV for your specific region.

1. Estimated Time
2. Actual Time

Hourly Rate for Work Performed – Est.

Description – When looking at each activity the PI performs, create time allowances for each activity. EX: A research physical exam for a certain study should take about 30 minutes. An informed consent for a specific study should take about 60 minutes, etc.

Pros – Less paperwork for the PI. Shows that much thought was put into compensation to avoid paying over FMV.

Cons – A robust tracking mechanism is needed to assure proper payments. Expense percentages will vary widely over different trial types.

Hourly Rate for Work Performed – Actual

Description– A PI would physically fill out documentation describing the exact time spent for a specific study, and the activity performed.

Pros – The most compliant method as you are compensating for actual documented time spent on the clinical trial.

Cons – Many PI's will resent the additional work needed on their part to track their time and effort. A robust tracking mechanism is needed to assure proper payments. Expense percentages will vary widely over different trial types.

Hourly Rate-Budgeting and Tracking

- Gold standard for compliance
- Hourly strategy aligns with most sponsor budget templates
- Payout Triggers
  - Actual Hours
    - - Payment triggers must be created in real time rather than preemptively
  - Estimated Hours
    - -Payment triggers can be linked to patient activity
- Time should be tracked
  - Estimated Hours
    - To prove FMV compliance
    - To determine what the actual salary should be
  - Actual Hours
    - To determine payout

Non Employed Investigators

- Assure that the PI Agreement includes language that PI will assume legal responsibility for their performance of services under the Clinical Trial Agreement (CTA)
- The PI Agreement is the Institution's opportunity to ensure the PI is complying with the same laws and regulations that the Sponsor is requesting the Institution to adhere to under the CTA

Other Considerations

- Be consistent with your payment methods for all PI's
- Assure investigator agrees with and signs all calculation documentation before **payment** is made
- Be sure to set payment timetable expectations (i.e. monthly, quarterly, when sponsor pays, etc.)
- Create a principal investigator payment written policy that you can share with all investigators so there is no confusion up front
- Provide a clear and concise explanation of each payment made to the investigator

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