Investigator Compensation: Understanding the Basics, Avoiding the Pitfalls

Geoffrey Schick, MBA, CHRC
Site Strategy Senior Consultant, WCG

It’s almost as though it were a secret.

Every site that conducts clinical trials should pay investigators, and the amount they pay and the methodology used can affect the success of a trial. The process is full of potential pitfalls. And, at least in my experience, sites are searching for the answer to this basic question: “How much should we pay investigators, and what methodology should we use?”

Yet, this topic is rarely discussed at industry meetings or in other public forums. At a recent MAGI session, we lifted the veil, and I’d like to share some of the key points.

Not surprisingly, we began with the legal implications. Any discussion of investigator compensation needs to start with the law, including the Anti-Kickback Statute, False Claims Act and the Physician Self-Referral Law (aka, the Stark Law).

UNDERSTAND THE LEGAL IMPLICATIONS

What sites pay physician investigators is considered part of their overall compensation amount, and there are very specific laws and regulations related to physician compensation. The Stark Law may be the most relevant; its personal services exception outlines when remuneration paid to a physician or to a practice for specific services is permissible. The requirements are as follows:

- The arrangement is put in writing, signed by the parties and specifies the services that are covered.
- The agreement covers all services furnished by the physician.
- The term of the agreement is at least one year.
- The compensation is set in advance, is consistent with fair market value and isn't determined based on the volume or value of any referrals or other business generated between the parties.
- The agreement is commercially reasonable: The aggregate services do not exceed what is reasonable and necessary for the legitimate business purpose of the arrangement.
- The arrangement does not involve an activity that violates federal or state law.

When you're working on compensation, it's important to keep in mind that although it can—and should—be motivational, it cannot provide too much of an incentive. It should be affordable, legally compliant, ethical and fair.

It must also be a fair market value (FMV) arrangement.

> *"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."*
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> —UNITED STATES V. CARTWRIGHT, UNITED STATES SUPREME COURT, 1973

FMV is baked into various regulations and statutes, including the Sunshine Act, the False Claims Act and the Anti-Kickback act. It must be defensible, documented, consistent and transparent.

The definition may sound simple enough, but unfortunately, there's no set formula for determining the fair market value for PI compensation. It often depends on such things as specialty, geography, physician experience and other market-based factors.

Sites can take steps to ensure they are indeed within FMV, including:

- **Be aware of physician compensation levels for services charged to third party payers (i.e. insurance):** Total payer reimbursement typically does not flow to the provider's paycheck, so be aware not to overpay for research services due to full payer reimbursement level.
- **Provide a full justification for all fees** charged into the clinical trials budget.
- **Create an hourly compensation fee schedule:** Engage internal support or external vendors to help you do this.
- Keep in mind that **neither a physician's going rate nor historical compensation necessarily constitute fair market value.**

I often talk to sites in terms of fair market value for medical procedures, including the professional fees earned by investigators for performing the service. In terms of research pricing, you don't want to be lower than Medicare because everyone is struggling with current Medicare margins, and you *definitely* don't want to be above full charge within your chargemaster. It could be a multiplier over Medicare (e.g., Medicare plus 50%) or a discount off charge (e.g., 80% of charge.) I'd say anything between Medicare and 100% of charge should be considered as fair game for fair market value. Perhaps look at some private insurance rates accepted in the institutions contracts. That's the argument that I would make with both finance and your compliance program.

MAGI offers an array of resources, including templates, to help organizations avoid any legal missteps, but ideally, you want your legal team to review any agreements.

WHAT'S BEING COMPENSATED?

PI compensation considerations typically include services that fall into one of three categories:

Clinical services paid for by the study. These include physician completed healthcare services such as office visits, EKG interpretations, radiology reads, etc. Professional fees that go along with interventional procedures for cardiac cath lab procedures, colonoscopy, surgeries, etc., also fall in this bucket. The study budget negotiated within the clinical trial agreement specifies which services the sponsor will provide payment to the site.

Time and effort type tasks or responsibilities. These include participation in study startup meetings, monitoring visits or reviewing safety reports (especially in oncology clinical trials). Safety reports can mushroom into a tremendous amount of work for study teams, and for physician investigators. A compensation model that addresses this category helps answer the question: When the investigator is expected to set aside a significant block of time, are you going to

make that investigator whole in terms of the time and effort?

Overall oversight and management of the study. What role does your principal investigator play that may be above and beyond what a sub-investigator might do?

The PI takes individual responsibility for the conduct of the clinical trial when s/he signs FDA form 1572. Does your compensation model recognize the oversight required of her/him in this role, including the additional potential risk?

AN ARRAY OF MODELS

So how should sites pay PIs? I've come across several different compensation models, including the following:

1 **A fixed fee for the study, regardless of investigator contribution:** This is an older model, one observed at an academic medical center in the Midwest. Clinical trials research was conducted and "owned" by the School of Medicine. The divisions shared in study revenues and the allocated dollars for investigator compensation were typically banked and organized in terms of compensation to investigators in future years or future studies. Each budget cycle, based on the number and complexity of studies—often evaluated by phase II, III, or IV—a "clinical research investigator" salary line was developed to reflect the expected workload of those active trials. Compensation for running those trials was then built into the regular payroll distributions for the future 12 months, often irrespective of actual enrollment levels.

With this model, an investigator knows that for each industry-sponsored clinical trial he or she brings into the organization, there will be consideration in a future salary line towards his or her total compensation. This is easy to calculate, but it may prove challenging to determine whether the payments fall within FMV. Additionally, if expected enrollment rates continually miss their mark there could be both financial and compliance questions that arise.

2 **Time and effort:** This methodology fits in well with meetings or office-based time, reviewing reports, participating on calls, things like that. The point is to capture the time and effort that the investigator is spending and to move some of the dollars paid for by the sponsor to where the work is being done. A large part of its appeal is that it's transparent, easy to justify and motivational. However, it's far more difficult to incorporate into actual patient interaction time or clinical time. In addition, it can be time consuming and cumbersome, especially when you're asking a physician or an investigator to keep track of her/his time. Sites must also carefully monitor billing: If billing the subject's insurance for routine services that are in the protocol, the site can't also compensate for those services. Compensating an investigator for research administrative time spent inside of a billable patient visit can be tricky to defend.

A common practice is to utilize a market-based hourly rate for investigator services that can be benchmarked easily. Salary calculations for emergency service physicians seem to be a common choice. Institutions with access to extensive salary benchmarking tools may choose to make the investigator rate specialty specific, if that is the agreed upon solution between research, medical group, finance and (of course) compliance.

3 **Percentage of study revenue/profit:** This is pretty much self-explanatory. The PI supervision fee falls into this category. You can base the percentage on specialty, investigator experience or some other factor. It must be negotiated with the sponsor, but it is justifiable. After all, the PI is the one who has agreed to be responsible for the conduct of the study. The fee recognizes that personal and professional responsibility the PI is undertaking.

The concept is similar to adding overhead % onto a clinical trial. Many sites negotiate an overhead rate – anywhere from 25% to 50% - applicable to all sponsor-reimbursed direct costs. The PI Supervision Fee – more often in the 5% to 15% range – is also built into the study budget, also based on sponsor-paid direct costs (not including the overhead rate!)

Be careful, though: The fee can inflate quickly if you have a clinical trial budget that is heavy on imaging services, interventional procedures, surgeries, etc., so you do have to keep an eye on what is reasonable. Careful attention should be made to determine whether the PI Supervision Fee falls within FMV.

4 **Research RVUs:** The RVU model works best for clinical services--anything with a CPT code. The standard RVU for a service's CPT code is utilized and multiplied against a rate of reimbursement established for research (or by specialty). However, a site need be wary of new, innovative services which may not have established CPT codes due to being so new. Medicare can establish T-codes (temporary CPT codes) to code the work, but T-code RVUs may not reflect the work being done. In its essence, the Research RVU model tries to mimic the prevalent RVU-based physician compensation programs that are prevalent across the country.

For research administration and clinical activities without CPT codes, the investigator either receives no RVU credit, or sites can develop research RVUs for common activities based on expected time to complete. Those activities could then be assigned uniform productivity values.

5 **Hybrid model:** As the name suggests, it's a combination of approaches. Every site varies in terms of their willingness to accept complexity, the amount of administrative time and effort they are willing to invest, etc. This approach allows them to determine the most effective approach for their situation. A simple example would be using a combination approach using Time and Effort tracking (#2) for administrative tasks, combined with Research RVUs (#4) to generate investigator compensation for work done to conduct a clinical trial.

FIGURING IT OUT

Whether you're creating a new investigator compensation system or modernizing a previous compensation plan, it can be tricky. Fortunately, WCG's Managed Research Solutions can help.

As the world's leading provider of Managed Research Solutions that measurably improve the quality and efficacy of clinical research, WCG is helping organizations re-imagine the research business model.

For more information visit
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