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Physician-Investigator Compensation

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Introduction

Physicians generally require financial compensation to conduct industry-sponsored clinical research. Their compensation must be sufficiently high and must be structured properly to motivate them to invest their time and energy, but not so high as to make the study uneconomical for the site or the study sponsor, to violate federal laws or professional standards, or to promote misconduct (e.g., enrolling unsuitable study participants).

Various investigator compensation structures are discussed in the literature.[2,7,8] Below are some guidelines for creating a compensation system that aligns investigator objectives with those of the clinical research site, while also complying with applicable laws, regulations, guidelines and professional standards. The article addresses compensation of physician-investigators, but it also generally applies to investigators with other qualifications.

Fair Market Value

Payments to physician-investigators that exceed fair market value (FMV) may violate the Stark Law and the Anti-Kickback Statute.[4] American Medical Association (AMA) guidelines on managing physician conflicts of interest in the conduct of clinical trials state that financial compensation should be at FMV.[1]

The concept of FMV extends back 120 years.[5] The Code of Federal Regulations defines it as "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."[6] The Centers for Medicare and Medicare Services define FMV as "the value in arm's length transactions, consistent with the price 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."[11] In 2003, the federal Office of Inspector General regulations stated: "Payments for research services should be fair market value for legitimate, reasonable and necessary services."[10]

However, these laws and guidelines do not explain how to determine FMV, which puts research sites at risk. Leaving aside the legal ramifications, if an investigator is paid above FMV, they may, for example, sign up for a poorly designed study, enroll unqualified patients in a study, pressure unwilling patients to enroll in a study or improperly prescribe a study sponsor's medications. If the investigator is paid below FMV, they may, for example, take shortcuts in study conduct, compromise human subjects' protection or not conduct the study at all.

Determination of FMV for investigator payments can take into account many factors, including activities performed (e.g., surgery vs. administrative tasks), medical specialty, geography and experience.[9,13] It also can vary within a range of, say, plus or minus 15 percent of the FMV determined by the site.

A physician's "going rate" or past compensation does not necessarily determine FMV. The value of administrative activities most likely differs between clinical research and clinical

services. Therefore, it is important to engage a third-party consultant to clearly differentiate between research and/or administrative services. Examples of research services include direct subject care during a study, while administrative services include those items external to subject care, such as monitoring visits and study paperwork.

To comply with FMV rules in making payments to investigators, take the following steps, keeping investigators informed through the entire process:

- **Create, maintain and comply with an FMV policy.** This policy should be consistent with the above requirements and be defensible in any government investigation.
- **Create, maintain and comply with an investigator fee schedule.** An external consulting firm can lend expertise and give credibility to the fee schedule.
- **Develop a chargemaster consistent with the investigator fee schedule.** Involve your billing team in developing the strategy. It is perfectly acceptable to charge a study sponsor more than you pay the investigator, but there should be a relatively consistent markup on these fees.
- **Explain investigator charges to study sponsors.** Include this explanation with your initial budget proposal.
- **Document any deviations from FMV.** If investigator fees are bundled into, for example, visit fees, document the allocation of charges. During budget negotiations, if the negotiators move fees around to get to a mutually agreeable bottom line, be careful not to violate FMV rules.

Investigator Compensation Structures

Investigators can contribute to a study in many ways,[1] so their compensation should be fair, motivational, affordable, practical, legal and agreeable.[6,7]

Investigator Compensation Based on Relative Value Units

Medicare created Relative Value Units (RVUs) to estimate productivity by calculating the relative level of physician time, skill and expertise employed in reimbursable activities. RVUs assume activities are performed in a defined amount of time and at a consistent level of quality. Medicare relies on these measures to establish payment levels for physician services as categorized by Current Procedural Terminology (CPT) codes.

Hospitals and other healthcare facilities can also use RVUs to manage and set compensation for staff physicians. By employing research RVUs (rRVUs) for clinical research-related activities, hospitals can smoothly integrate clinical research into their physician management and compensation systems. Investigators earn a set number of rRVUs for clinical research activities (e.g., reading a protocol, screening a patient, having an informed consent discussion or conducting a routine follow-up visit).

Because of the extra effort involved in clinical research, rRVUs can be set higher than comparable clinical RVUs (e.g., at 150 percent). (Clinical research informed consent discussions can be much higher.) Because of the extra work and other factors, activities in clinical research can have higher FMVs than clinical RVUs.[4]

Since many rRVUs do not have CPT codes, a clinical research coding system can be employed.[12] Although many so-called "hidden" clinical research costs are not included in study budgets, they should still earn rRVUs.

Other Investigator Compensation Structures

In addition to RVU-based compensation, investigator compensation can be structured in the following ways:

- **Fixed fee or percentage.** The site pays the investigator a fixed fee or percentage of the study's revenue, regardless of their contributions. These options are simple to manage. However, it is difficult to assess whether they accurately reflect the investigator's contribution or the FMV of the investigator's services. These options may not align site and investigator motivations.
- **Salary.** The site pays the investigator a full-time or part-time salary for working on clinical trials.
- **Hourly rate.** The site compensates the investigator a specialty-specific hourly rate, which may be based on the nature of the activities performed.
- **Fee for service.** The site compensates the investigator for specific activities performed. This option takes relatively more time to administer. However, it motivates investigators to perform the contracted services, although not necessarily at the level of quality and timeliness desired. This option can work well for subinvestigators.
- **Hybrid model.** The site combines two or more of the compensation options above. For example, fixed fees could be utilized for activities, such as site initiation or monitoring visits, which are relatively consistent from study to study. Fee for service could be utilized for study procedures that vary from study to study and visit to visit.

Compensation structures should take into account the following considerations:

- The study sponsor and the study participant or their third-party payor cannot both be billed for the same activity.
- Clearly document the investigator's activities including, where appropriate, the time spent on administrative tasks associated with the clinical trial.
- Document mutual expectations in contracts that comply with guidelines set forth in the Personal Service Exception provision of the Stark Law and the Personal Services and Management Contracts Safe Harbor provision of the Anti-Kickback Statute.[4]
- Compensate investigators for their activities in the patient enrollment process. Do not compensate them based on the number of study participants enrolled. FDA, ICH and AMA rules prohibit bonuses, finder's fees or pay-for-performance to investigators based on the number of participants enrolled in or completing a clinical study.[3]
- Compensation can be paid to individual investigators, shared evenly across a group of investigators, or paid to their department or business entity.

Conclusion

Investigator compensation must comply with laws, regulations, guidelines and professional standards. However, within the bounds of FMV, sites have substantial flexibility in designing compensation structures that align investigator objectives with those of the clinical research site.

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