

Investigator Compensation: Motivation vs. Regulatory Compliance

By Payal Cramer

Physician-investigators play a central role in clinical research. Through both professional and regulatory obligations, they bear significant responsibilities in gathering data, protecting subjects, and supervising the conduct of the trial. Most physician-investigators must also balance research with their clinical practice. Thus, fairly compensating and motivating physicians to serve as investigators is a challenge for research sites.

To add to the challenge, for research sites that conduct business with federal healthcare programs, payments to physicians must comply with the federal Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). In addition, for certain of these research sites, the compensation arrangement must also comply with the Physician Self-Referral Law ("Stark Law"). Thus, even if a site has unlimited funds, it must limit and structure its payments to physician-investigators to minimize the possibility of severe penalties under the law.

Anti-Kickback Statute

The AKS was enacted to protect federal healthcare programs from fraud and abuse. The AKS places a broad prohibition on providers, suppliers and manufacturers *participating in* federal healthcare programs by proscribing remuneration of any kind to induce referrals or the purchase of items or services covered by federal healthcare programs (42 U.S.C. § 1320a-7b (2015)). For the purposes of the AKS, remuneration is defined broadly and includes any kickback, bribe or rebate offered directly or indirectly, overtly or covertly, in cash or in kind.

Certain transactions and arrangements are not subject to AKS enforcement because they fall under a statutory exemption or a regulatory safe harbor. Because violation of the AKS has an intent component, compensation arrangements that do not meet all the requirements of a safe harbor are not *per se* illegal. However, the arrangement should be structured to comply with as many requirements of the most applicable safe harbor as possible to minimize risk of violation of the AKS.

The safe harbors most relevant to arrangements between research sites and physician investigators are the personal services and management contracts safe harbor and the employment safe harbor. The regulatory requirements for these safe harbors are set forth below:

The Personal Services and Management Contracts Safe Harbor

Under the personal services and management contracts safe harbor, a payment by a research site to a physician investigator as compensation for services is not "remuneration" if:

- The parties have an agreement that is set out in writing, signed by the parties, and covers all of the services to be provided by the investigator.
- If the agreement is for less than full-time services, it must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

- The term of the agreement is for not less than one year, which might affect how the agreement may be amended.
- The aggregate compensation paid to the investigator over the term of the agreement is set in advance and is consistent with fair market value ("FMV") in arms-length transactions. The compensation should reflect payment for all services covered by the agreement and may be "set in advance" in the form of a formula instead of an exact dollar amount. The aggregate compensation must not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under state or federal healthcare programs. While this requirement does not prohibit payment for clinical trial services provided to beneficiaries of federal healthcare programs, it does prohibit increasing the rate of compensation for investigators simply because they are high enrollers or referrers.
- The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
- The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

The Employment Safe Harbor

Payments made by an employer to an employee as compensation for services within the scope of the employment arrangement are not "remuneration" if the site and investigator relationship meets the common law rules for an employer-employee relationship under the Internal Revenue Code, which are based on behavioral and financial characteristics (69 Fed. Reg. 16,087).

Violation of the AKS may result in criminal, civil and administrative enforcement. It may also give rise to FCA liability. The FCA prohibits knowingly submitting or causing to be submitted false claims for payment to U.S. government officials. Thus, submission of a claim resulting from an arrangement that violates AKS might also lead to FCA enforcement, followed by criminal and civil penalties under the FCA.

Stark Law

The Stark Law prohibits (a) physicians from making referrals for designated health services for which payment may be made under the Medicare or Medicaid programs to any entity with which the physician has a financial relationship and (b) an entity from filing a claim to Medicare or Medicaid for designated health services furnished pursuant to a prohibited referral (42 U.S.C. 1395nn). Designated health services include: (a) clinical laboratory services; (b) physical therapy, occupational therapy, and outpatient speech-language pathology services; (c) radiology and certain other imaging services; (d) radiation therapy services and supplies; (e) durable medical equipment and supplies; (f) parenteral and enteral nutrients, equipment and supplies; (g) prosthetics, orthotics and prosthetic devices and supplies; (h) home health services; (i) outpatient prescription drugs; (j) inpatient and outpatient hospital services.

Arrangements that meet the requirements of Stark Law exceptions are permitted under the law. Stark Law is a strict liability statute, which means that any arrangement that does not meet all of the criteria for an exception is in violation of the law. The exceptions most relevant to arrangements between research sites and physician investigators are the *bona fide* employment arrangement exception and the *bona fide* personal services exception.

The Employment Arrangement Exception

Similar to the AKS exception, the Stark Law provides an exception when a physician is considered an employee, provided the relationship meets the criteria utilized by the IRS (56 Fed. Reg. 35,981). In addition, the arrangement must meet the following requirements: (a) the employment is for identifiable services; (b) the amount of remuneration paid to the physician is consistent with FMV and is not determined in a manner that takes into account, directly or indirectly, the volume or value of referrals by the employed physician; and (c) the remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

The Personal Services Exception

The personal services exception might be applicable to arrangements where a physician provides services to the research site and receives compensation or some other value for such services. The arrangement satisfies the exception if:

- The arrangement is in writing, signed by the parties, and specifies the services covered by the arrangement, including all services the physician or immediate family member will furnish to the entity.
- The term of the agreement is for not less than one year (if terminated during the first year, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement).
- The contract for aggregate services does not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- Services do not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law.
- The compensation is set in advance, does not exceed FMV, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties (42 U.S.C. § 1395nn-(e)(3)(a); 42 C.F.R. § 411.357(d)). As with the Personal Services and Management Contracts Safe Harbor under the Anti-Kickback Statute, the compensation may be "set in advance" in the form of a formula, and the rate of compensation must not be increased simply because an investigator is a high enroller or referrer.

Regulatory Considerations for Various Payment Models

Considerations that affect compliance with AKS and the Stark Law are addressed below for various payment models. However, this list of considerations is not exhaustive and will vary with the facts of each arrangement. In addition, the safe harbor and exception requirements outlined above must also be met.

Per Subject Payment. Under the per-subject compensation model, research sites pay investigators a fixed amount per research subject enrolled in the trial. Typically, payments are made at certain specified milestones.

- Must set fees based on the services provided.
- Must account for subjects who do not complete all study visits.

Hourly Wage. Research sites may compensate investigators by market-based, specialty-specific hourly rates for their time.

- In determining the hourly wage, sites must take into account the FMV of the services the investigator is providing, along with the investigator's expertise in the field.

- If investigator is billing a third party/subject for routine services that are in the protocol, that time should not be excluded from the hourly payment.
- Investigators must document their time and associated activities and submit these records to the site for payment.

Global Payments. Research sites may pay investigators a lump sum or global payment to serve as the investigator for the trial.

- When paying a percentage, it must accurately reflect the FMV of the investigator's services.

Fee-for-Service. Research sites may pay investigators a fixed amount per service performed. Thus, the services are unbundled and compensated separately.

- If the investigator is billing a third party/subject for routine services that are in the protocol, the site should not also compensate for those services.

Salary. Where investigators are employed by the research site, investigators may be compensated for research-related services as part of their base salary. For these employees, study-related work might simply be considered part of their regular duties and compensation is included in their base salary.

- Since research services are built into the salary, sites should set forth research expectations in the employment agreement.

Work RVU Calculation. Relative Value Units (RVUs) are measures constructed by Medicare to estimate productivity by calculating the relative level of physician time, skill, training and expertise that Medicare relies upon to establish payment levels for physicians' services. Physician services are described by Current Procedural Terminology (CPT) codes. This compensation model is typical when a hospital also employs the physician-investigator as a clinician. In this compensation model, the investigator earns RVU credits when he or she performs clinical services with CPT codes that are part of the clinical study.

- Must account for research time with no corresponding CPT code.
 - For research administration and clinical activities without CPT codes, the investigator receives no RVU credit and is paid market-based, specialty-specific hourly rates.
 - Sites may develop research RVUs for compensating clinician-investigators for research services. Research activities can then be assigned uniform productivity values. These assigned values are converted to RVUs, creating an overall measure of investigator productivity.
- Incorporates motivation into an existing RVU model.

Motivation and Behavior

Any compensation system must recognize the realities of human motivation and behavior — it is unreasonable to establish a compensation system that rewards physician-investigators for certain behaviors and then expects them to forgo that compensation by engaging in other behaviors.

Different payment models provide different motivations. For example, a fixed payment per procedure encourages physician-investigators to perform the maximum number of procedures but relies on their integrity to perform them well and on schedule. In contrast, payment per hour encourages physician-investigators to maximize the time spent on the procedures but relies on their integrity to perform them correctly, efficiently and on schedule. Hybrid payment models can deal with such issues but can easily become overcomplicated. Much of this complexity can be avoided by engaging in periodic reviews of

the quantity, quality, timeliness and cost of the procedures performed and the payments made.

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