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Gimme Shelter: Anti-Kickback Safe Harbors and Clinical Trial Agreements

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Introduction

The federal anti-kickback statute, one of the most potent weapons in the government's arsenal in the war on fraud and abuse, is not only generating criminal prosecutions and huge settlements; it is also changing the way consulting agreements, including clinical trial agreements (CTAs), must be structured. For nearly a decade, the government has warned against using research studies to mask what are really marketing efforts designed to provide financial incentives to doctors to get them to use a new drug or device. However, the line between research and product development is often blurred. A lone email from a mid-level sales executive discussing anticipated revenue benefits from a research study, even one whose primary purpose is to generate valuable data, may be enough to arouse the government's suspicions. Further, courts allow private parties (aka "whistleblowers") to seek civil penalties for anti-kickback violations using the False Claims Act.[1] As a result, whistleblowers and their attorneys have successfully brought lawsuits advancing novel applications of the statute to seemingly legitimate transactions. Such lawsuits are likely to mushroom in the future.

An earlier article focused on the potential application of the federal False Claims Act to clinical trial sponsors and related the types of fraudulent activities found in recent settlement agreements to problematic contractual provisions found in CTAs.[2] Many of these same contractual provisions and financial arrangements also implicate the federal anti-kickback statute. In fact, these two statutes are often invoked in conjunction. The government's contention is that all claims for reimbursement made while an illegal kickback arrangement exists constitute false claims under the theory the provider would have falsely certified that it is in compliance with all applicable laws in its cost reports filed with Medicare during the same period.[3]

This article will review the basic elements of the anti-kickback statute, its application to CTAs, a recent enforcement example, and the availability of protection from prosecution if an arrangement meets the requirements of an applicable "safe harbor." However, the notion of safe harbors can create a trap for the unwary. If any one of the required elements under a particular safe harbor is not met, the safe harbor does not apply, potentially resulting in criminal, civil and administrative enforcement actions for perceived violations of the statute.

The article concludes that, from a business and economic perspective, it may be impossible, or at least inadvisable in some cases, to draft CTAs in strict compliance with all of the requirements of the safe harbor regulation. However, it certainly is prudent to satisfy as many as possible when full compliance is not attainable.

The Anti-Kickback Statute

On the books since 1972, the main purpose of the federal anti-kickback statute (42 U.S.C. §1320a-7b(b)(2)) is to protect both patients and federal healthcare programs from fraud and abuse that can result when healthcare decisions are, in part, based on the corrupting influence of money. The reach of the anti-kickback statute is extremely broad, punishing anyone who:

> Knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person… to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program.[4]

Criminal penalties that can be imposed include up to five years imprisonment plus fines of up to $25,000 for each violation. Conviction will also lead to automatic exclusion from federal healthcare programs. In addition, the Balanced Budget Act of 1997 added a civil monetary penalty of $50,000 per act plus up to three times the amount of illegal remuneration. The Office of Inspector General (OIG) can also impose administrative sanctions on civil violators, excluding them from participation in Medicare.

Knowing and willful conduct (i.e., intent) is a necessary element of this criminal offense, and must be proven by the government "beyond a reasonable doubt." While the legislature has repeatedly designated the "scienter" requirement in fraud and abuse laws as "knowingly and willfully," it has failed to provide a clear threshold definition of this phrase. As a result, circuit courts have created a spectrum of definitions ranging from a strict liability approach (i.e., liability without establishing purposeful intent) to focusing on whether the defendant knew that federal law prohibited offering or paying remuneration to induce referrals and engaged in the prohibited conduct with the specific intent to disobey the law. Other courts have developed standards of culpability that lie somewhere in between.

In a 1985 Third Circuit Court of Appeals decision (U.S. v. Greber), the court held that the statute has been violated if one purpose of the remuneration is to induce referrals, notwithstanding the fact that there may be other legitimate purposes for which payment is made.[5] Several other courts have affirmed this interpretation. However, 10 years later the Ninth Circuit Court of Appeals dealt a major setback to government prosecutors by ruling that the government must prove defendants knew that federal law "prohibited offering or paying remuneration to induce referrals," and must have "engaged in prohibited conduct with the specific intent to disobey the law." [6] The Eighth and Eleventh Circuit Courts of Appeals adopted more of an intermediate standard, ruling that the government must prove actual knowledge that the remuneration is wrongful, rather than proof of intent to violate a known legal duty.[7] Since the U.S. Supreme Court has yet to hear a case that would resolve the issue, the standard is still evolving.

Defendants can always assert a lack of the requisite intent in anti-kickback cases. From a practical standpoint, however, the intent element seldom comes into play. Faced with the threat of criminal, civil and administrative sanctions, including exclusion from federal healthcare programs, most fraud and abuse investigations result in a settlement. Few defendants have been willing to stay the course through trial.

Safe Harbors

Because the statute is so broad and covers virtually any financial relationship between a healthcare provider and a referral source, concerns arose within the industry that relatively innocuous business arrangements – that may even be beneficial to the public – could be subject to criminal prosecution or administrative sanction. Congress responded by requiring the OIG to issue regulations defining specific "safe harbors" for various payment and business practices that, while potentially prohibited by the anti-kickback statute, would not be prosecuted.[8] Since then, numerous safe harbor regulations have been promulgated.

Healthcare providers and others may voluntarily seek to comply with the provisions of the safe harbor regulations or not. If a particular arrangement does not fit squarely in a safe

harbor, it will not be protected from potential criminal and civil prosecution. However, this does not mean the arrangement is necessarily illegal. Arrangements not falling into a safe harbor must be analyzed on a case-by-case basis to see if they comply with the statute. This case-by-case analysis is an important aspect of federal anti-kickback law because it is frequently impossible or inadvisable to meet all of the requirements of any given safe harbor.

Personal Services Safe Harbor

The safe harbor most relevant to CTAs is the one for "personal services and management contracts."[9] For a CTA to be protected under this safe harbor, all of the following requirements must be met:

- The agreement must be in writing and signed by both parties.
- The agreement must specify the services to be provided.
- 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.
- The term of the agreement must be for one year or longer.
- The aggregate compensation to be paid over the term of the agreement must be set in advance and be consistent with fair market value (FMV) in arm's-length transactions and not be determined in a manner that takes into account the value or volume of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under federal or state healthcare programs.
- The services performed under the agreement must not involve the counseling (i.e., advising on) or promotion of a business arrangement or other activity that violates any state or federal law.
- The services contracted for must not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the arrangement.

As noted above, allegations of anti-kickback violations can always be defended, perhaps successfully, by arguing that the parties did not act knowingly and willfully. However, CTAs should not be structured on the hope that an anti-kickback case can be successfully defended in the courts. The safe harbors, including the personal services safe harbor, are intended to provide some certainty for planning purposes. On the other hand, some speculation on the part of the parties is still required: Accurately predicting in writing all services to be rendered, as well as accurately estimating the fair market value of those services, can be as nebulous as the concept of intent.

Parties who are uncertain whether a particular arrangement qualifies for safe harbor protection may request an advisory opinion from the OIG. However, the advisory opinion process has its limitations. First, and perhaps most importantly, the OIG will not address issues regarding the FMV of any particular arrangement. Further, favorable advisory opinions are binding only on the requestors and may not be relied upon by any other individual or entity. Finally, although the Department of Justice (DOJ) reviews all advisory opinions before they are issued, neither the DOJ nor any other agency, except the Department of Health and Human Services (DHHS), is bound by advisory opinions.

How "Safe" are Safe Harbors?

In 1994, the OIG proposed a general rule that would preclude safe harbor protection for "sham" transactions.[10] Sham transactions are those that satisfy the requirements of a safe harbor regulation on paper, but in reality are a façade for improper payments for referrals. The OIG declined to incorporate such a rule *per se* in the final regulations, as commenters

indicated that the regulations were already overly broad.[11] However, in the 1999 final rule, the OIG indicated that it would be entitled to investigate a transaction meeting the safe harbor requirements if the form of an arrangement did not correlate with its substance. Specifically, the OIG stated:

> We emphasize, however, that for purposes of determining compliance with the safe harbors, we will evaluate both the form and the substance of arrangements. To be protected, the form must accurately reflect the substance. As we have explained in the context of space and equipment rentals: If a sham contract is entered into, which on paper looks like it complies with these provisions but where there is no intent to have the space or equipment used or the services provided, then clearly we will look behind the contract and find that, in reality, payments are based on referrals.

The OIG has identified "indicia of questionable research" that may cover disguised kickbacks and therefore represent sham transactions, regardless of the personal services safe harbor. Indicia of questionable research include research contracts that originate through the company's sales and marketing functions and post-marketing studies used as a pretense for product promotion.[12]

Post-marketing studies are conducted for a variety of purposes. Commonly, post-marketing studies are either mandated by the FDA as a condition for approval or are being conducted for the stated purpose of discovering scientifically relevant information. Although the majority of these studies have designs and methods that allow for these stated purposes to be addressed, some studies are either explicitly intended to promote or have the effect of promoting the sponsor's product in the eyes of the OIG.

Acknowledging that it is often difficult to make distinctions between the scientific and promotional purposes of studies, the OIG has stated that informed judgments can be made by looking at the underlying financial arrangements, the design and methodology of the studies, the scientific validity and future use of the data collected, the source of control of the study design, and placement of the studies with physician-investigators. Thus, in addition to structuring the CTA to fit into the personal services safe harbor, "prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing."[13]

Enforcement Example

The following example specifically addresses financial arrangements for clinical research. Further, the remedial actions imposed on these companies reflect the importance the government places on the elements of the personal services safe harbor.

On September 27, 2007, the DOJ announced that five medical device companies that account for almost 95% of the market in artificial hip and knee implants avoided criminal prosecution over financial inducements paid to orthopedic surgeons by agreeing to new corporate compliance procedures and federal monitoring under 18-month "non-prosecution" or "deferred prosecution" agreements.[14] Specifically, the companies were accused of using consulting agreements as inducements to use their products. From 2002 through 2006, surgeons who had agreements with these companies were allegedly "paid tens to hundreds of thousands of dollars per year for consulting contracts and were often lavished with trips and other expensive perquisites." According to the press release, the government's investigation revealed instances in which the surgeons did little or no work for the financial payments under the consulting agreements, "but did agree to exclusively use the paying company's products."

Four of the five companies – Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet, Inc., and Smith & Nephew, Inc. – entered into Deferred Prosecution Agreements (DPAs) that are scheduled to expire 18 months after the date of execution of the agreement if all required reforms are completed. The fifth company, Stryker Orthopedics, Inc., was the first of the five companies to voluntarily cooperate with the DOJ and as a result entered into a Non-Prosecution Agreement (NPA). Under the NPA, Stryker is required to implement all of the reforms imposed on the other four companies, including 18 months of federal monitoring.

In addition to employing a federal monitor to review compliance with the agreements, as well as to review all new and existing consulting relationships, the agreements require each of the five companies to conduct annual "Needs Assessments." These Needs Assessments "must reflect the Company's expected, commercially reasonable needs for all Consulting Services to fulfill its medical, clinical training, educational, and research and development needs." [15]

The agreements specifically define "consulting agreements" covered under the settlement as including "agreements for… clinical studies, product development and license agreements, research, and professional services agreements." Further, the following requirements related to CTAs and/or the personal services safe harbor can be found in the Stryker NPA:

1. "All consulting agreements must be in writing and executed by the Compliance Officer, the President, the Chief Legal Officer, the Director of R&D for product development and research agreements, and the Director of Clinical for clinical services agreements (including clinical trials, clinical studies, follow-up visits)."
2. "All consulting agreements for services to be rendered in 2008 and thereafter must be for a term of the calendar year, with the exception of product development agreements that could result in the payment of royalties, clinical agreements, and external research agreements, which may be for a length appropriate to the type of service being rendered, upon approval of the federal monitor. All consulting agreements must identify the specific services to be provided, as defined by the Needs Assessment and any approved Modification thereto, and specify the rate to be paid for each service. Consultants must be paid only for the actual time expended in providing services, in hourly billing increments or other reasonable quantitative measure as identified in the Needs Assessment."
3. "A company employee or representative must be present for every service, except that the appointed federal monitor, upon application by the company's Compliance Office, may exempt certain services from this requirement (such as collection of clinical study data, travel or preparation time)."
4. "For all consulting agreements entered into after the effective date, the company will make payments to consultants at a fair market value hourly rate of no more than $500 per hour for time actually expended by the consultant in performing the services. If the company wants to make payments to a consultant at a higher hourly rate or at a different rate because of the consultant's special expertise or the nature of the service (such as a per patient rate for clinical studies), the company must obtain or have obtained a fair market value analysis conducted by an independent organization with expertise in valuation as approved or accepted by the federal monitor."
5. "The company may not make payments to consultants for collection of clinical data unless there is a written agreement defining the required procedures and protocol and the amount of clinical data to be collected by the consultant, pre-approved by the Director of Clinical."

6. "The company may not make payments to consultants for research unless there is a written agreement defining the required procedures and protocol, pre-approved by the Director of Research and Development. The company is prohibited from making unrestricted grants to consultants."

Common Pitfalls in CTAs

Although not specifically addressed in the personal services safe harbor, the first shortcoming of many CTAs may be related to the selection of the principal investigators (PIs). Understandably, sponsors may want to sign up the most influential members of the medical community. Unfortunately, the government may contend that the selection of the PIs is overly influenced by the desire to reward committed current and past prescribers of the company's products, rather than for the substantive contribution the individual PIs can make to the research study at hand.

Part of the problem seems to stem from the organizational unit within the sponsor that selects the PIs and/or funds the research, especially when the sales or marketing departments are involved, as opposed to the research and development or medical affairs departments. Even when the sales or marketing departments do not control the decision-making process, these departments typically weigh in with their opinions and are sometimes involved with contract negotiations. As demonstrated in the above enforcement example, the selection of PIs, as well as the negotiation of CTAs, should not involve sales or marketing personnel and research funding should not be a line item in these departments' budgets.

Assuming the arrangement is not a sham transaction, does not involve the counseling or promotion of a business arrangement that violates state or federal laws, and has a commercially reasonable business purpose other than product promotion, CTAs should be drafted to comply with the remaining elements of the personal services safe harbor as closely as possible. This section of the article will focus on a discussion of these elements.

Duties and Responsibilities

A common problem seen in many CTAs is the manner in which the duties of the site and investigator are defined. Frequently, the contracts themselves deal only with vague generalities regarding the scope of the work the research team is being asked to undertake. For example, there are often broad references to providing "such services as are required to successfully complete the study in accordance with the protocol." The CTA may provide few specifics about activities outside the protocol, such as investigator meetings, site monitoring visits, and data queries. Such broad language, by itself, makes it difficult to objectively measure the services the study sponsor is actually getting in exchange for its payments under the agreement, as well as the value of those services.

Similarly, many CTAs do not adequately define the research team's expected time commitment. There is nothing in the agreement indicating a certain number of hours an individual task is expected to take, nor is there necessarily any documentation at the site indicating the actual time expended. Rather, at most large academic and research organizations, the percentage of an individual research team member's salary to be charged to the contract is established in advance by the site at the time the contract is awarded and a corresponding research account is set up. That percentage is then charged to the research account each pay period through the site's automated payroll system, regardless of activity. This lack of specificity in the CTA, coupled with the lack of documentation of actual time expended at the site, may make the arrangement suspect when large payments are involved and there is little documentation for actual hours expended. It is, of course, much

easier to add specificity to the CTA and study budget than to change an institution's cost accounting and reimbursement system.

Specified Intervals and Payments

If the contract requires services on a less than full-time basis, it must specify the "schedule of intervals, their precise length and the exact payment for each interval" that the site will receive. In other words, when and how often the services will be required, what services will be required at each such interval, and the payment the site will receive once those services have been rendered. The use of milestone, per-visit or per-activity payments, in conjunction with the protocol's schedule of events, meets this requirement.

Term

To meet the requirements of the personal services safe harbor, the term of the agreement must be for not less than one year. At first blush, this requirement seems simple enough. However, in the context of a clinical trial and in light of the OIG's perspective on termination clauses, it may not be in the best interests of sponsors or investigative sites to draft CTAs to comply with the term requirement.

In response to public comment, the OIG addressed the 1-year term requirement for the "Space and Equipment Rental" and "Personal Services and Management" safe harbors in its preamble to the November 19, 1999 final rule clarifying the initial safe harbors.[16] Specifically, the commenter asked whether the 1-year term requirement would be satisfied: (1) if the lease or contract contained a "for cause" termination clause, or (2) if the contract permitted termination with or without cause, provided there was also a clause that prohibits parties terminating without cause from entering into any further relationships for the balance of the required 1-year term. According to the OIG:

> The 1-year term requirement ensures that protected leases or contracts cannot be readjusted frequently based on the number of referrals between the parties. Although not specifically stated in the safe harbor regulation, a 'for cause' termination clause that (i) specifies the conditions under which the contract may be terminated 'for cause' and (ii) operates in conjunction with an absolute prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original 1-year term would satisfy the 1-year term requirement. We remain concerned, however, that 'without cause' termination provisions could be used by unscrupulous parties to create sham leases and contracts. This could occur, for example, where the parties enter into an agreement to pay a sum of money upfront for services to be performed over a period of time. Parties could disguise payments for referrals by terminating the agreement without cause after payment, but before performance of any services. A 1-year prohibition on renegotiation of further financial arrangements would be meaningless in such circumstances.

CTAs almost always include termination without cause provisions and almost never contain "an absolute prohibition on renegotiation or further financial arrangements for the original 1-year period." This is not to say that CTAs should attempt to specify all the conditions under which the agreement can be terminated with cause and contain an absolute prohibition on further financial arrangements between the sponsor and the site. There are numerous legitimate business reasons for not doing so.

First, it is difficult to foresee and list all the reasons for which a sponsor or site may want to terminate the agreement. Certainly, a sponsor would want to terminate the agreement with a site that is not enrolling subjects and a site would want to terminate the agreement out of concerns over subject safety, but there are many other legitimate reasons on both sides. It is probably better to include a provision for termination without cause rather than try to

speculate about all of the reasons the parties might have for wanting to terminate an agreement, thereby limiting their ability to terminate the agreement for an unforeseen reason not previously enumerated in a termination-for-cause provision.

Second, the parties would not want to limit their ability to renegotiate the terms of the CTA or enter into other CTAs for additional trials. For example, if one site has met its enrollment targets while another site has yet to enroll, the sponsor may want to terminate the non-enrolling site and amend the CTA with the other site to allow for additional enrollment. Similarly, if one trial is stopped for legitimate reasons, why should sponsors and sites be prohibited from working together on another trial during the remainder of the original one-year term?

Compensation

As stated numerous times by the OIG, the main purpose of the anti-kickback statute is to protect both patients and federal healthcare programs from fraud and abuse that can result when healthcare decisions are, in part, based on the corrupting influence of money. Certain types of compensation arrangements and/or contract provisions are easily interpreted by the OIG as violating the anti-kickback statute by improperly influencing a physician's independent judgment. The theory is that, faced with two or more treatment options, a physician may be tempted to refer a patient for enrollment into a clinical trial in exchange for a "finder's fee" or, if the PI is the treating physician, enroll the patient in a clinical trial in order to receive a direct or indirect enrollment incentive from the study sponsor, which may or may not be in the patient's best interest. Consider the following real-world examples:

- "In recognition that increased enrollment puts added requirements on the research staff, Sponsor will compensate the Institution $5,000 per every 10 eligible patients enrolled through 30-day follow-up." Why does the site only incur additional costs in increments of every ten eligible subjects?
- "In recognition of additional costs that will be incurred by investigators and institutions in screening patients, reviewing records and meeting protocol requirements on an expedited basis, Sponsor agrees to provide supplemental compensation as follows: The sum of $12,000 for the enrollment of at least 7 patients within a quarter. This is in addition to the compensation provided for above." How does the site incur additional costs for performing the same services more quickly? Moreover, the site will not receive any additional compensation if it enrolls less than 7 subjects in any given quarter, even if it has incurred additional costs.
- "In consideration of the PI's participation in all four of the Sponsor's trials [A, B, C and D], Sponsor will reimburse Institution $60,000 per year for a period of two years to defray the cost of a full-time CRC. Payment will be made after the PI has (1) identified the CRC and (2) enrolled [X] number of patients in [trial D]." Shouldn't the CTAs for the individual trials, (A, B, C and D) have already taken into account the study coordinator's time?

To meet the requirements of the personal services safe harbor, "The aggregate compensation to be paid over the term of the agreement must be set in advance and be consistent with fair market value in arms-length transactions and not be determined in a manner that takes into account the value or volume of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under federal or state healthcare programs." Many CTAs set forth aggregate compensation by stating a per capita payment for x number of subjects the site may enroll. However, without more detail, per capita payments evidence a troubling lack of forethought regarding how much the research site and investigator should be paid, especially if the duties are not well-defined. Regurgitating the safe harbor's FMV requirement in the CTA does not relieve either

party from determining FMV. For example, the following provision is commonly found in CTAs with per-capita payments:

> The parties acknowledge that the compensation set forth in Exhibit B represents the fair market value of the services for which support will be provided, negotiated in an arm's-length transaction and has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the Institution, Investigator and Sponsor.

Further, representatives of some large, well-known pharmaceutical companies have stated at recent conferences that they give research sites budget templates listing only per-visit or per-capita payments due to "the anti-kickback statute." This novel "see no evil" strategy provides evidence that very little, if any, true negotiations are taking place. It also invites government auditors to allocate payments as they see fit.

Failure to negotiate FMV per activity may be particularly problematic in multi-site trials where one site has allocated the per capita payment entirely to unspecified "research efforts" while another site has allocated a much lesser percentage to efforts and a greater percentage to items and services that it has determined are not billable to third-party payers. At best, the first site may be subject to a charge of double-billing under the False Claims Act. The worst case scenario would be to also charge the sponsor with violations of both the anti-kickback statute and the False Claims Act for encouraging false claims through shoddy management of its CTAs.

As noted in the enforcement example above, the device manufacturers must make payments at an hourly rate not to exceed $500 per hour for time actually expended by the consultant in performing the services. "If the company wants to make payments to a consultant at a higher hourly rate or at a different hourly rate because of the consultant's special expertise or the nature of the service (such as a per patient rate for clinical studies), the company must obtain or have obtained a fair market value analysis conducted by an independent organization with expertise in valuation as approved or accepted by the federal monitor." If sponsors of multi-site trials continue the practice of letting individual sites allocate per capita payments as they see fit, resulting in significantly different payment rates for PI efforts, they may find themselves scrambling to document FMV and justify what is indefensible in the government's eyes.

Determining FMV

Since the personal services safe harbor and past DOJ/OIG enforcement actions focus on the PI as the referral source, this article will not discuss FMV for facility fees (e.g., laboratory and other diagnostic services). However, unallocated per capita payments or payments allocated to PI efforts in excess of FMV in the eyes of the OIG could lead to retrospective reallocation of the payments and assertions that the payments were intended as payment for laboratories and other diagnostics services that were billed to Medicare and other federal health programs.

The Internal Revenue Service (IRS) defines FMV as "the price of a service between a willing buyer and a willing seller, neither being under any compulsion to buy or sell and both having a reasonable knowledge of the relevant facts." While this definition helps in determining FMV under other safe harbors with readily available marketplace data (i.e., equipment rentals), it does not provide much guidance for determining FMV for PI efforts, which can vary dramatically by specialty, geography and years of experience. A common approach to determining FMV for PI efforts is to determine an hourly rate by physician specialty based on national benchmark sources (e.g., the Medical Group Management Association). These hourly rates can then be applied to the total number of hours projected in the budget for investigator time. Likewise, a reasonable (i.e., defensible) hourly rate for

study coordinator time and effort should be established and documented. Experience with previous studies and commercial databases of clinical research fees can help establish FMV rates.

However a FMV rate is calculated and documented, the amount of PI effort to which it is applied should be somewhat consistent among CTAs in multi-site trials. Both the OIG and DOJ have signaled in the above enforcement example that inconsistent payment or work levels among different consultants without an independent FMV analysis supporting the higher payments will invite closer scrutiny.

Conclusion

It is a lot easier to spot a "sham" research agreement than it is to draft a legitimate CTA within the parameters of the personal services safe harbor. As stated earlier, some speculation on the part of the parties to a CTA is still required. For example, it may be nearly impossible to accurately "specify the schedule of intervals for required services, their precise length and the exact charge for such intervals," particularly for services that may or may not be required (e.g., adverse event reporting, review of protocol amendments, responding to data queries on case report forms, etc.). While it is tempting to insert a provision allowing for renegotiation of the budget should a site's costs exceed those originally estimated, renegotiation of the agreement within the 1-year term may take the CTA outside the protection of the safe harbor. This is not to say that such clauses or renegotiations automatically make the arrangement illegal, only that the protection afforded the arrangement by strict compliance with the safe harbor elements may be lost. Arrangements not falling squarely in a safe harbor are analyzed on a case-by-case basis. If the unanticipated costs are carefully tracked, quantified and documented prior to a renegotiation taking place and the renegotiated payments represent FMV, the CTA should still pass an anti-kickback analysis.

On the other hand, if the amount of time estimated to complete study tasks is overestimated or, in fact, the services are never required, resulting in a significant residual balance or profit to the site, the government might argue that the per capita payments were in excess of FMV or that paid-for services were never rendered. At least one former federal prosecutor, James Sheehan, has taken the position at various conferences that residual balances should be returned to the sponsor of the trial regardless of how insignificant the balance may be.

If a CTA cannot be drafted entirely within the requirements of the safe harbor, the next best thing is to meet as many of the requirements as possible and document the arrangement on a case-by-case basis, with supporting justification for the expected services, anticipated time commitment, reasonableness of the compensation, and actual performance of the services. Government officials are likely to carefully scrutinize poorly drafted CTAs that lack these elements.

References

1. See, e.g., U.S. ex. rel. Thompson v. Columbia/HCA Healthcare Corporation, 125 F.3d 899 (5th Cir. 1997)
2. Are Clinical Trial Sponsors the Next Target for False Claims Act Enforcement?; Journal of Clinical Research Best Practices; Vol. 3, No. 10, October 2007
3. Id. at 1.
4. 42 U.S.C. § 1320a-7(b)(b)(1); 42 U.C.S. § 1320a-7(b)(b)(2)
5. U.S. v. Greber, 760 F.2d at 68 (3rd Cir. 1985)
6. Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)

7. U.S. v. Jain, 93 F.3d 436 (8th Cir. 1996) and U.S. v. Starks, 157 F.3d 833 (11th Cir. 1998), respectively
8. See, section 14 of Public Law 100-93 "Medicare and Medicaid Patient and Program Protection Act of 1987"
9. 42 CFR § 1001.952(d)
10. 59 FR at 37,202, 37203 (July 21, 1994)
11. Id.
12. 64 FR at 63,530
13. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR at 23735, 23736
14. DOJ press release last accessed 1/9/2008 at www.usdoj.gov/usao/nj/press/index.html
15. See, Stryker's Non Prosecution Agreement
16. 64 FR 63526

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