

Focus Arrangements CIAs: A Good Model for Stark/ Anti-kickback Statute Compliance Programs?

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The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) has been using corporate integrity agreements (CIAs) as an alternative to exclusion under the OIG's exclusionary authorities for as long as I can remember. While CIAs have always felt, and will likely continue to feel, punitive to organizations that are offered a CIA as an alternative to being excluded, they have also become, as a general matter, a good model for establishing an active, effective compliance program.

CIAs include some requirements or activities that no provider would undertake unless required to do so. (The best examples are probably reporting about all compliance program activities to the OIG and providing written and signed certifications to the OIG that the organization is in compliance with federal health care program requirements.) Most of the core requirements of the OIG's standard CIA form, however, are in line with what best practice organizations are doing to establish and operate compliance programs voluntarily, and the OIG has done a good job in recent years of making many CIA requirements malleable to the structural and operational realities of the organizations that are required to implement them. For example, for the last several years, rather than requiring a prescribed training regimen CIAs have instead required organizations subject to CIA requirements (CIA-obligated organizations) to establish their own compliance training plan.

CIAs also have begun to address more specifically the conduct that resulted in a settlement and CIA. We now see the OIG enter into CIAs that are—in their compliance and independent review requirements—focused on claims issues, quality of services provided to beneficiaries, marketing and sales efforts, and compliance with the Stark law and anti-kickback statute in referral source financial arrangements. (This last form of CIA is

often referred to as a “Focus Arrangements CIA.”) The Focus Arrangements CIA form is used in instances where an organization has entered into a settlement of alleged noncompliance with the Stark law and/or anti-kickback statute.

Focus Arrangements CIAs require many of the same core compliance program elements that are required in all CIAs generally—without regard to the subject matter of the settlement that resulted in the CIA. So, Focus Arrangements CIAs—like all CIAs—require appointment of a compliance officer that reports periodically to a board or board committee; an annual board resolution confirming oversight by the organization’s board or board committee; implementation of a management level compliance committee; annual certifications from selected executives and leaders; a code of conduct; training programs (generally including training for “arrangements covered persons”); and a “disclosure program” including a hotline or similar mechanisms for use in reporting concerns about possible noncompliance.

What makes a Focus Arrangements CIA unique is the Focus Arrangements Procedures that CIA-obligated organizations are required to implement; and independent review organization (IRO) requirements that include a “Systems Review” of the organization’s Focus Arrangements Procedures, and a “Transactions Review” of a randomly selected sample of Focus Arrangements to confirm that the Focus Arrangements have adhered to the Focus Arrangements Procedures and to the requirements of the CIA. The Focus Arrangements Procedures are intended to mitigate the risk that an organization’s financial relationship with a source or recipient of referrals to or from the CIA-obligated organization will result in a violation of the anti-kickback statute or the Stark law.

Does the OIG’s current Focus Arrangements CIA form provide a good

model for an Arrangements Compliance Program in a provider organization? To answer the question well, it is important to understand first the purpose of an active, effective Stark and anti-kickback, or “Arrangements” Compliance Program (“Arrangements Compliance Program”).¹ (After all, how can you determine whether a program is effective, or a model is appropriate, if you have no role, purpose, or outcomes in mind to measure against?)

STRATEGY FOR A CORPORATE COMPLIANCE PROGRAM

Several years ago, I was asked to evaluate the current state of an organization’s compliance program and to make recommendations on staffing or other areas where the organization might need to consider additional investments or improvements as they sought to strengthen the compliance program. I have done many compliance program evaluations and have often jumped directly into a process of understanding the structural design and operation of the compliance program I am evaluating. This time, however, I decided I would begin the process by first understanding what leaders in the organization wanted and expected from their organizational compliance program—by understanding what organizational leaders believed the strategy of the compliance program should be—so that I could, at least in part, evaluate whether the compliance program was meeting organizational leader’s expectations.

I began that evaluation process by first asking organizational leaders to explain their view or understanding of the strategy for the organization’s compliance program. I was amazed. To a person not one organization’s leader could articulate a clear vision, purpose, or strategy for their organizational compliance program. Most of the leaders I spoke with were thoughtful and talked about some of the activities they had seen the compliance staff engaged in (*e.g.*, training, investigations).

There were references to avoidance of particular kinds of compliance risk. One leader quipped that the compliance program was there to “keep me out of jail.” (My thought was—I hope you won’t mind if we aim a little higher!) A few looked puzzled, and one leader said, “No one has ever asked us to think about the compliance program in *that way*.” As I pondered this experience, I realized that this organization was not all that unique. Most organizations just don’t think of compliance as a strategy-driven activity.

As I have worked with boards and leadership teams in years since I have continued to ask the strategy and vision questions, but I’ve also been sharing my thoughts about what the right strategy for a compliance program in a health care provider organization might be. In general, I’ve concluded that the core strategies for a mature, effective compliance program include:

1. prevention;
2. detection and correction; and
3. defense.

Preventing compliance problems from occurring should be the core strategy of any mature, active, effective compliance program. Compliance programs help to prevent problems by raising awareness about standards and requirements; by providing mechanisms for reporting concerns and asking questions; by supporting a culture that expects people to (as I heard one compliance officer characterize it recently) “do the right things for the right reasons;” by facilitating or conducting monitoring processes that help the organization stay focused on doing things the right/required way. If you think about it, at least half of the activities occurring to create and/or maintain the seven core elements of a compliance program are focused on prevention. Consider the roles played by leadership; policies and procedures; training and communication; risk assessment; reporting mechanism; monitoring and

auditing—each of these core compliance program elements has an important role to play in helping to prevent problems before they occur. I often tell my compliance program evaluation clients that when I see a program devoting at least 50 percent of its resources (staff, consulting budget, etc.) to prevention, I can be fairly certain that I am seeing a mature—and likely effective—compliance program. While I am not aware of any practical way to scientifically measure where compliance program efforts are being spent, I generally find that those working in compliance functions have a good sense of whether their time is being spent on proactive (preventative) or reactive tasks. Prevention is, I think, the number one strategy of any well-functioning compliance program.

Detecting and correcting instances of noncompliance that do occur is a second primary strategy of a well-functioning compliance program. As with prevention, several core compliance program activities contribute to the fulfillment of this strategy. The organization’s reporting mechanisms (hotline, other) and non-retaliation policies provide a vehicle for receiving notice when problems may be occurring. Properly structured and working investigation processes help to assure that issues that do occur are fully understood so that appropriate and timely response can be made by the organization. A program that is operating well will respond to investigation findings with corrective action, expansion of training or other compliance processes, discipline, or even self-disclosure to governmental authorities when that is appropriate.

The **defensive** role of a compliance program also comes into play when compliance failures have occurred or are alleged. If an organization is able to demonstrate active and effective compliance processes, and timely investigation, resolution and self-disclosure of instances of noncompliance, it is often possible to avoid harsher

consequences when inadvertent problems do occur. A primary theme of the Sentencing Guidelines is that a mature, well documented compliance program can avoid up to 90 percent of the penalties that might otherwise be incurred as a result of misconduct. Many of the early victories in my compliance career involved helping organizations avoid or limit CIA requirements by demonstrating that the organization already had in place an active compliance program that was capable of having an effect on organizational compliance. While the OIG's position has shifted—avoiding a CIA now generally requires that the organization found the problem first and self-disclosed it to government authorities—these early victories are great examples of how a compliance program can serve to mitigate the harm caused by instances of noncompliance.

WHAT COMPLIANCE RISKS SHOULD THE ORGANIZATION BE FOCUSED ON?

Another important consideration when establishing the strategy for an organizational compliance program is the kinds of risks that the compliance program's prevention, detection and correction, and response initiatives should be focused on. While the specific risks faced by each organization will vary, in my experience, in a health care provider setting there are three broad subject matter areas where the risk of noncompliance is greatest and where well designed and effective compliance programs expend most of their resources. These broad risk areas include:

- financial relationships with referral sources (Stark and anti-kickback statute risks);
- documentation, coding, and billing for services to federal health care programs (False Claims Act-related risks); and
- privacy and security of protected health information (Health Insurance Portability and Accountability Act (HIPAA) and Health Information

Technology for Economical and Clinical Health (HITECH) Act risks).

The recently updated U.S. Department of Justice *Evaluation of Corporate compliance programs* document (the “DOJ evaluation document”) highlights the importance of identifying the right risks for mitigation by the compliance program. The DOJ's Justice Manual, in its *Principles of Federal Prosecution of Business Organizations*, requires prosecutors to consider the effectiveness of existing or improved compliance programs when making charging and resolution decisions.² The DOJ's updated evaluation document is intended to assist prosecutors in their required evaluation of compliance programs. It indicates that the starting point for a prosecutor's evaluation of a compliance program is to understand “how the company has identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risks.”³

In a recently published survey focused on current trends in health care compliance programs, health care compliance officers identified their top compliance risk priorities as:

Highest Risk Areas/Highest Priorities for Compliance Officers ⁴
64%: HIPAA Security/Cybersecurity
50%: HIPAA Privacy
44%: Claims Accuracy
41%: Government Audits
33%: Financial Arrangements with Referral Sources

The surveyors noted—as did I in reading the survey—that this ranking of risk priorities seems to differ significantly from priorities of the health care fraud and abuse enforcement community. The surveyors cited a statistic that 93 percent of DOJ civil fraud cases result from whistleblowers

alleging violations of the anti-kickback statute and the Stark law. It also has been my experience that the most costly and difficult compliance problems that provider organizations face are in the Stark and anti-kickback arena. There does seem—at least in these survey results—to be a disconnect between the risk environment that most health care providers operate in and the priorities established for many health care compliance programs.

It may be that this disconnect derives in part from the fact that most organization's legal counsels are heavily involved in structuring and helping to negotiate referral source financial arrangements. In many organizations the legal department “owns” questions about compliance with Stark or the anti-kickback statute. The assumption might be, then, that the lawyers have compliance covered in this area and this is not, therefore, a significant compliance risk that the compliance function should or needs to be focused on. Delegating full responsibility for compliance with the Stark and anti-kickback statute requirements to the legal department alone, however, may be a mistake.

Over the course of my career as compliance officer, attorney, and consultant, I have evaluated or overseen the evaluation of thousands of physician and other financial relationships with referral sources, and my teams and I have identified hundreds of referral source arrangements that have failed for various reasons to meet the strict requirements of the Stark law or have become potential violations of the anti-kickback statute. With a very limited number of exceptions, all of the arrangements that ended up as Stark or anti-kickback statute compliance problems were structured and reviewed up front by knowledgeable attorneys (and in virtually every case these attorneys did their job of establishing and structuring arrangements that met Stark exception and anti-kickback statute safe harbor requirements and were “legal” arrangements when they were

delivered to management to implement.) I can count on one hand the number of times that I have seen an arrangement that was noncompliant because the lawyers did not do their up-front job well. However, I have helped organizations self-disclose literally hundreds of noncompliant physician and other referral source financial arrangements.

What has happened? The reality is that compliance issues in the Stark and anti-kickback arena—at least for organizations that are making an effort to properly structure their arrangements up front—almost always occur after the lawyers deliver the final documents to management so that the arrangements in question can be initiated. Final contracts are not signed. Documentation isn't maintained. The arrangement changes and veers away from the carefully crafted (and expensive) fair market value (FMV) opinion—and no one updates the contract or the FMV opinion to keep up with changes in how the arrangement is operating. The contract expires, the arrangement changes, and no one is watching as the significance of the compliance issues continues to grow.

In my view, a fully functioning Arrangements Compliance Program, that addresses both up-front requirements for establishing lawful arrangements and assures that the arrangements are properly managed to assure that compliance is maintained, is at the heart of any well-designed provider compliance program. The strategy to prevent, detect, correct, and establish defensive responses is critical in this most significant compliance risks area for many health care provider organizations.

BRIEF OVERVIEW OF ANTI-KICKBACK STATUTE AND STARK—WHO IS AT RISK?

The health care anti-kickback statute⁵ was originally enacted by Congress in its current form effective in 1978. In general, the anti-kickback statute prohibits:

- knowingly and willfully,
- offering, giving, soliciting, or receiving,
- any remuneration (directly or indirectly, in cash or in kind),
- in exchange:
 - for a referral of health care business, or
 - for purchasing, leasing, or otherwise doing business that is passed on as costs to federal health care programs.

The anti-kickback statute applies to any referrals or costs associated with any federally funded health care program. The anti-kickback statute is enforced both criminally and civilly. Maximum criminal penalties under the statute are up to \$100,000 and/or up to 10 years in prison for each kickback violation. Anti-kickback statute enforcement often, however, takes the form of a *qui tam* pursued under the False Claims Act, in which the relator claims damages on behalf of the government that equal three times the amount of improper claims filed as the result of kickback tainted referrals, along with the inflation adjusted penalty of \$11,463 to \$22,927 per improper claim.

The Stark law⁶ was originally enacted by Congress in 1989. Stark was expanded significantly in 1993 when Congress added several categories of “designated health services” to the original Stark prohibition. The prohibitions of the Stark law are avoided by assuring that a financial relationship with a physician strictly adheres to at least one of a series of regulatory Stark exceptions.⁷ As a general matter, the Stark rule mandates that:

- If a **physician**⁸ (or his or her immediate family member) has a **financial relationship** with an **entity**, the financial relationship must meet all requirements of an applicable **exception**, or
 - the physician may not **refer designated health services (DHS)** to the entity,
 - the entity may not bill Medicare for improperly referred DHS (the Stark

law can also be used to reach improper billings to the Medicaid programs),

- Medicare may not pay for improperly billed services, and
- the entity has an affirmative obligation to return any Medicare (and Medicaid) payments resulting from improperly billed DHS.

As with the anti-kickback statute, enforcement of Stark often takes the form of a *qui tam* complaint alleging that an improper physician financial arrangement resulted in tainted claims that are then pursued as False Claims by relators and by the DOJ when it elects to intervene.

Both the anti-kickback statute and the Stark law are broadly crafted. Any financial relationship, any ownership or investment interest, any payment, or any in kind offer, solicitation, gift, receipt, or exchange—if in exchange for referrals (or, for Stark, if between an entity and a referring physician as defined by Stark) may implicate these laws. Any organization or person participating in the health care marketplace could be at risk for a violation of the anti-kickback statute, and any party to a physician-entity financial relationship (as defined by Stark) is at risk if a relevant Stark exception is not strictly adhered to.

WHEN ARE FOCUS ARRANGEMENTS CIAs UTILIZED? WHEN DO FOCUS ARRANGEMENTS PROCEDURES APPLY?

Focus Arrangements CIAs have migrated over the years as the OIG has continued to develop its understanding of what makes compliance programs work in health care organizations. As a general matter the basic structure for Stark and anti-kickback statute compliance requirements in Focus Arrangements CIAs has been consistent for more than 10 years, dating back at least as far as the seminal Tenet Healthcare Corporation CIA in 2006.⁹ The Focus Arrangements Procedures or compliance requirements outlined in Focus Arrangements CIAs apply to “Focus

Arrangements.” While Focus Arrangements CIAs take nearly two pages to define what qualifies as a “Focus Arrangement,” the definition of Focus Arrangements generally includes:

- a. every arrangement or transaction that involves, directly or indirectly, the offer or payment of anything of value and is between the CIA-obligated organization and any actual source or recipient of health care business or referrals to *or from* the CIA-obligated organization (this part of the definition is intended to capture and assure that compliance requirements apply to arrangements that may implicate the anti-kickback statute); and
- b. every financial relationship between the CIA-obligated organization and a physician (or immediate family member of a physician) who makes a referral of designated health services to the CIA-obligated organization (this part of the Focus Arrangements definition is intended to assure that compliance requirements apply to and address arrangements that may implicate the Stark law and regulations).

The definition in (a) above for arrangements that may implicate the anti-kickback statute was amended recently to include arrangements with corresponding referrals *from* the CIA-obligated organization. (Historically, the definition focused only on arrangements with corresponding referrals *to* the CIA-obligated organization.) Most provider organizations are in the position to both make and receive referrals, so this focus on arrangements with corresponding referrals both to and from an organization makes sense for organizations that are developing voluntary arrangements compliance processes to address possible anti-kickback risks.

The definition in (b) above for arrangements that may implicate Stark is further refined in Focus Arrangements CIAs to exclude arrangements that satisfy one of several exceptions to the Stark law and

regulations—so long as the CIA-obligated organization maintains sufficient documentation to demonstrate compliance with the applicable exception.¹⁰ Since the language excluding several kinds of financial relationships from CIA requirements applies *only if* the CIA-obligated organization maintains documentation of compliance with the relevant Stark exception, CIA-obligated organizations (and organizations establishing voluntary Compliance Programs in this area) should still establish appropriate compliance policies and processes even for the financial relationships that implicate Stark but are excluded from CIA coverage.

WHAT FOCUS ARRANGEMENTS PROCEDURES REQUIRE (AND 2018 FOCUS ARRANGEMENTS PROCEDURES CHANGES)

In 2018, the OIG made several enhancements to its Focus Arrangements CIA form. To evaluate the Focus Arrangements Procedures requirements, I have used requirements from two currently active Focus Arrangements CIAs: (1) the CIA with Halifax Hospital Medical Center and Halifax Staffing, Inc. (March 10, 2014),¹¹ and (2) the CIA with William Beaumont Hospital (July 31, 2018),¹² and have noted as redline (strikethrough or underlining) in quoting each of the 10 Focus Arrangements Procedures requirements that follow the changes that were made to the OIG’s standard Focus Arrangements CIA form in 2018. It is important to note that the OIG rarely negotiates alternative language for these requirements, so the language highlighted below is generally “standard” for any organization entering a Focus Arrangements CIA. The standard Focus Arrangements Procedures (with recent updates noted) include the following:

1. *“Creating and/or maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the information specified in the*

[Focus Arrangements Procedures] below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System)."

The first Focus Arrangements Procedures requirement is, stated simply, a requirement that the CIA-obligated organization must establish and maintain a contract database (known in CIA parlance as the Focus Arrangements Tracking System or "FATS") that incorporates all relevant information and documentation for all of its Focus Arrangements. Some organizations have established home grown systems to meet this requirement, but there are several good contract management systems available for purchase or lease—and most such systems if set up and utilized properly will satisfy this first Focus Arrangements Procedures requirement.

The OIG updated the FATS requirement in 2018 to specify that the contract management system or FATS must incorporate all the information specified by all of the Focus Arrangements Procedures requirements. This means that the contract management system should be one that can capture and store in accessible fields key contract terms (*e.g.*, parties, compensation rates, effective date, expiration date, other key terms) and should be a database that can be used to store scanned or electronic versions of the documents related to the arrangement (*e.g.*, the signed contract, documentation of business need and rationale, fair market value opinion or information, approvals, documentation of required reviews, etc.)

In simple terms: the contract database or FATS needs to be the central repository for all documents and information required to properly establish and manage the Focus Arrangement and to defend against allegations that the arrangement has violated the anti-kickback statute or Stark. This kind of comprehensive repository is essential to any robust Arrangements Compliance Program.

When an organization finds itself defending the propriety of a Focus Arrangement, it is almost always the case that the required defense happens five or even 10 years after the arrangement was originally initiated. Finding signed contracts, FMV opinions, approvals, time sheets, and other important documentation is almost always essential to a successful defense. A robust contract management system that stores and maintains all key documentation (and procedures that require contract files to be completely populated and maintained) will help to ward off claims of impropriety or to facilitate a successful defense if such claims do arise.

A robust contract management system will also help an organization do a better job of managing active arrangements to maintain compliance. A good contract management system will include a capability to provide email or other notices of expiring contracts (so that renewals can be timely initiated and completed); it will help organizations assure proper payments and manage key contract terms and limitations; and it can help the organization identify and prevent duplicate and overlapping services, thereby preventing anti-kickback liability that might arise from paying for unnecessary or duplicate services.

2. "Documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review and approval of all Focus Arrangements;"

This second Focus Arrangements Procedures requirement was added to the Focus Arrangement CIA form in 2018. I believe it is, in significant part, intended to assure accountability for each arrangement that creates risk of anti-kickback statute or Stark noncompliance. There is something about having to put your name on it—having to sign on the dotted line—that makes a responsible person think twice about whether all "i's"

are dotted and “t’s” are crossed. While I have found in most organizations that, at some level, documentation of who was responsible for negotiation, review, and approval of “Focus Arrangements” happens naturally, making it a matter of policy that this is part of the documentation for each Focus Arrangement adds a level of accountability that will be valuable in assuring compliance. Remember too, the 2018 amendments to the Focus Arrangements Procedures require that the information required by this procedure (names and positions of persons involved in negotiation, review, and approval) must be recorded in the contract management system (the FATS) to meet CIA requirements.

This Focus Arrangements Procedures requirement makes it clear that the responsible parties it identifies are “arrangements covered persons” for purposes of operating the CIA. Anyone who has ever had experience implementing or operating a CIA knows that identification of covered persons is an essential step in assuring that those who are required by the CIA to receive training are in fact trained. Recent CIAs require that training for arrangements covered persons must include information about: the anti-kickback statute and Stark law; organizational policies and processes intended to assure compliance in this area; personal obligations to assure compliance in this area; legal sanctions under the anti-kickback statute and Stark law; and examples of violations of the anti-kickback statute and Stark law. This kind of in-depth training on the risks associated with referral source arrangements is key to compliance program success whether the Arrangements Compliance Program is implemented voluntarily or because it is required by a CIA.

3. *“Tracking all remuneration to and from all parties to Focus Arrangements, to ensure that the parties are complying with the financial terms of the Focus Arrangements*

and that the Focus Arrangements are commercially reasonable.”

For most organizations, maintaining compliance with this Focus Arrangements Procedures requirement as it relates to payments made *by* the organization is already, at some level, a matter of good business practice. Put another way: for most Focus Arrangements where a CIA-obligated organization is providing remuneration to a referral source, I have found that organizations do not have to establish new systems and processes to satisfy the basic tenet of this requirement. Payments to physicians or physician organizations that are independent contractors are already tracked in an organization’s accounts payable system, as are payments to other vendors that might be parties to Focus Arrangements. Payments to employed physicians are recorded in the payroll system. What CIA-obligated organizations have sometimes *not* realized is that the reason for this “tracking remuneration” requirement is to facilitate confirmation that each payment conforms with contract terms and limitations and, more importantly, that this confirmation should occur before each payment is made. This is likely why the OIG expanded the “tracking remuneration” requirement in 2018 to specify that its purpose was to assure adherence to the financial terms of the Focus Arrangement.

The process called for by this Focus Arrangements Procedure makes sense for any Arrangements Compliance Program. I have seen many Focus Arrangements that slid into noncompliance because payments were made that were not consistent with contract terms. The contract stated a \$150/hour rate, but the physician at some point insisted on \$175/hour, and no amendment was made to the contract to allow for this new hourly rate. Or, the contract allowed payment for a maximum of 20 medical director hours each month, but the physician submitted timesheets

for 30+ hours—and all 30+ hours were paid without question. Similar problems with employed physician relationships have resulted in significant settlements in recent years. A physician's contract specifies base salary plus a bonus that is calculated based on the physician's RVU production, but no one pays attention to the RVUs that are counted, and the organization later learns that compensation, in part, was “related to the volume or value of referrals” because RVUs associate with radiology, lab, or other technical services referred by the physician were included in calculating her bonus compensation.

The reason that this “tracking remuneration” requirement was added to Focus Arrangements Procedures many years ago was to *prevent improper payments*: it was to help assure that with every payment someone who understands the implications of paying in a manner that is not consistent with the contract or with legal requirements is confirming that the payment that they are approving will not cause problems. With this in mind, most CIA-obligated organizations expand on the basic accounts payable or payroll system “tracking” to assure that the information that is maintained facilitates the needed review and approval of payments as they occur.

Where I have worked with organizations on their compliance processes in this area I have recommended a payment approval process for payments to independent contractors that asks three simple questions to assure compliance: (1) is the contract still in effect (not expired); (2) is the payment that I'm approving consistent with the contract (hourly rate, limits, etc.); and (3) is the physician's documentation of the services she provided adequate to support this payment (see the Focus Arrangements Procedures requirement numbered 5 below for more on this third approval requirement). If the responsible-approving manager is thinking through these three questions

with each independent contractor payment he or she approves, an organization will not process many payments that later cause compliance problems. The approvals look a little different for an employed physician on an RVU-based base plus bonus compensation model, or for an arrangement with a device manufacturer. However, if the right review and approval process is added for every payment to a potential or actual referral source, and if payments are tracked to facilitate approvals, the organization will likely avoid many compliance problems that might otherwise occur.

One additional caveat: with limited exceptions for payments that will never vary (*e.g.*, bi-monthly salary payments for employed physicians) an organization's arrangements compliance policies should prohibit automatic recurring payments for physician and other referral source compensation arrangements. If there is any chance that the payment might vary from month to month, someone knowledgeable should review and approve every payment. For example, if a medical director arrangement allows payment for up to 20 hours of medical director service, don't make this an automatic payment for 20 hours each month, even if you are certain that the physician will always provide at least the maximum number of reimbursable hours. Reviewing and approving each monthly payment is critical to avoiding compliance missteps.

4. “Documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s).”

While there has consistently been (in recent years) a Focus Arrangements Procedures requirement that a CIA-obligated organization must have a process for determining and documenting the fair market value of every Focus Arrangement, the requirement quoted immediately above that the CIA-obligated organization must document contextual information about the fair market value support it develops for each Focus Arrangement was added to the Focus Arrangements Procedures requirements in 2018. This new requirement was likely added to assure that fair market value determinations are timely made and remain relevant to the arrangement in question, and to create additional accountability for this important requirement.

Confirming that remuneration in a Focus Arrangement is set at fair market value is a core element of most Stark exceptions and of most anti-kickback statute safe harbors. The OIG has taken the position that payments in excess of fair market value may violate the anti-kickback statute. Assuring a robust process for determining and documenting fair market value for each referral source arrangement is important to assuring compliance in this area of risk. The added accountability that is created by this new Focus Arrangements Procedure should be considered for adoption by organizations establishing voluntary Arrangements Compliance Programs.

5. *"Tracking service and activity logs to ensue that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable)."*

This Focus Arrangements Procedures requirement was not changed in the 2018 revisions to the Focus Arrangement CIA form. But, as with requirement number 3 above related to tracking remuneration (which was amended to explain its

purpose), if the goal is to promote and assure compliance, organizations implementing this requirement need to do a bit more than just "track" the service and activity logs in question.

When are service or activity logs required in a fully functioning Arrangements Compliance Program? This requirement is driven by compensation and other arrangements where the compensation, or value of other remuneration received or given, may vary based on the number of hours, or number of units of service, provided by the physician or other referral source that is being compensated (or is providing compensation for services or other benefits received from the CIA-obligated organization). Medical director and call coverage arrangements are probably the most common arrangements where service or activity logs are required. Medical directors typically submit monthly time logs that document the hours of service and a description of what was done or accomplished. Physicians providing call coverage pursuant to a call coverage arrangement generally invoice a hospital for the days the physician was on call. In both cases, well-designed processes require a certification from the physician that services were provided as claimed on the time or service log. Other common arrangements that might require a service or activity log include:

- (1) a service arrangement where a physician group is paid a fixed dollar amount for each radiology service that the group interprets (a log of services the physicians in the group performed and seek payment for would likely make sense for this arrangement);
- (2) a physician employment arrangement with compensation based on RVU production (here, the employer organization will want to assure that it is logging and evaluating the physician's RVUs);
- (3) a time share lease arrangement pursuant to which a physician has access to and utilizes space periodically based

on a schedule established in the lease (here, a log of the physician's actual days and hours of use would document adherences to the lease terms.)

There are other common, and not-so-common, Focus Arrangements where a service or activity log will help an organization assure adherence to contract terms and requirements and will help assure and document that payments that are made are consistent with the contract terms and are commercially reasonable. Effective arrangements compliance policies will require time sheets, detailed invoices, service and activity logs, for certain specified arrangements—and will require manager initiating arrangements that do not fit in the specified categories to consider whether a log, timesheet, or other documentation should be required to help assure that the arrangement adheres to contract terms.

A literal reading of this Focus Arrangements Procedure requirement might lead a CIA-obligated organization to develop a logging system (*i.e.*, a spreadsheet or other logging process) where it records each medical director time sheet, call coverage invoice, and other service or activity log that it receives. But, while this requirement certainly contemplates that good compliance process will include consistently receiving and maintaining good documentation of services and activities, mature Arrangements Compliance Programs also incorporate this documentation in more meaningful ways. For example, medical director contracts and call coverage agreements stipulate that physicians will only receive payment if contractually required medical director time sheets or call coverage invoices are completed and submitted as required by the contract. And the organization's policies prohibit payment unless this required documentation has been received *and reviewed by the manager responsible for approving each monthly payment* to confirm that the documented

services are consistent with those payable under the contract (see the discussion regarding payment approval under Focus Arrangements Procedure requirement 3 above.)

6. *"Monitoring the use of lease space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable)."*

Many of the compliance problems I have encountered over the years with medical office leases would have been avoided, or at least significantly curtailed, if the organization leasing space to physicians had maintained an active program for monitoring the physician-tenant's use of space and compliance with lease terms. Most commercial landlords do similar monitoring as a matter of good business practice. A typical commercial landlord will stop by periodically to confirm that there aren't any unsafe conditions on the premises; to assure that the tenant isn't doing anything illegal in the premises; to confirm that the fire exits and smoke detectors are working properly.

For medical office building leases that create a risk of Stark or anti-kickback statute noncompliance, a periodic walk-through should simply add some "check-ins" designed to monitor for activities that might create Stark or anti-kickback statute noncompliance. Confirm in a walk-through that the physician hasn't moved into any adjacent space that doesn't belong to him. Confirm that he hasn't taken on any sub-tenants that aren't allowed by the lease and may create compliance problems. Confirm that any shared common space is being used in accordance with lease terms and legal requirements. A good Stark/ anti-kickback statute monitoring program might also include confirming that rent is being paid timely, that CPI increases have been calculated and

applied, and that resulting additional rent is being collected. It might include confirming that any services (e.g., Internet, janitorial, trash) being provided by the landlord are included in the “full-service” lease rate.

This Focus Arrangements Procedure suggests that similar monitoring might be helpful in other areas—not just with medical office lease arrangements. In my experience organizations often struggle to identify other areas where similar monitoring might help avoid compliance problems, but I believe it is a good practice to think about this requirement with each new Focus Arrangement that is entered with a referral source. It may also be valuable to consider where supplies, equipment, or other resources might be at risk of use by physicians or other referral sources for their own benefit.

If a physician is leasing equipment, would it make sense to monitor and assure that she is utilizing the equipment as specified in the lease? If hospital employed mid-level providers are available to assist at surgery, should you monitor to assure that the physicians aren’t billing for work done by the hospital employed mid-levels? If you’ve made computers and printers available to medical staff members to facilitate completion of hospital medical records, can you and should you monitor to assure that the computers and printers aren’t being used for personal business? Appropriate monitoring protocols can help an organization avoid unintended compliance problems.

7. *“Establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a*

process for specifying and documenting the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement.”

The importance of compliance processes that facilitate careful ongoing management of Focus Arrangements to assure that they maintain compliance has been highlighted above, but a well-structured upfront process for assuring that new arrangements are consistent with applicable Stark exceptions and anti-kickback safe harbors when they are formed is also *essential* to a Focus Arrangements Compliance Program. If the arrangement isn’t set up properly to begin with, it won’t matter what is done to maintain compliance if the ship that is the noncompliant Focus Arrangement has already sailed. The upfront process should include documentation and evaluation of the business need or rationale (to help assure that the arrangement is “commercially reasonable”); it should include a process for determining and documenting fair market value; and it should include a review by knowledgeable counsel who confirms that the arrangement is consistent in form with applicable Stark exceptions and anti-kickback safe harbors.

Establishing and documenting business need or rationale is the responsibility of the manager or leader who is initiating the arrangement, and this responsibility should be assigned to management in the organization’s compliance policies. Establishing and documenting the need or rationale for an arrangement can be a challenge for management, in part, I think, because the “need” or “rationale” may often seem self-evident to the manager or leader who is required to establish and document the business case.

There is no regulatorily required or common format for documenting business need and rationale. I generally

encourage responsible managers to put together several paragraphs describing what the arrangement will accomplish; why the proposed party is the best party to complete the task; describing any competitive bidding process or alternatives that were considered; explaining why the amount of time, services, etc., is necessary to accomplish objectives of the arrangement; explaining what the duties or responsibilities of the contracted parties will be. The documentation that best supports business need or rational will vary from one arrangement to the next. A periodic community needs assessment will help to support physician recruitment and employment decisions. The business plan for a new cancer center may be one of the best supporting documents to help establish the need for a new cancer center medical director.

As has already been discussed above, an organization's processes for determining and documenting the fair market value of the remuneration contemplated by an arrangement is also essential to good compliance outcomes in the Focus Arrangement arena. Here there is more regulatory guidance, and many common and best practices for an organization to emulate as it establishes its own requirements for documenting fair market value. There are also salary surveys and other tools commercially available to assist with keeping the process cost-effective. For organizations that are setting up and operating multiple Focus Arrangements of differing kinds, there will likely be wisdom in interacting with one or more experts on valuation as the organization establishes its policies, procedures, and processes in this important area. Understanding when a salary survey is adequate and how to use the survey data to support a physician arrangement, when it might be necessary to utilize an outside evaluation firm, and what kind of market valuation support is most relevant to establishing the value of a leasehold space may all be relevant

questions that need to be answered as an organization establishes its compliance requirements and procedures.

Delving into the details in this complex area is beyond the scope of this article, but requirements and processes that are crafted after careful consideration of the kinds of arrangements that the organization is managing, and the relevant implications of regulatory requirements and commentary, and industry practice, will be essential to effective Focus Arrangements compliance processes. It is worth noting that in the most recent revisions to the Focus Arrangements independent review organization (IRO) requirements, the CIA form requires that the IRO either "possess expertise in fair market valuation issues or [has] the ability to associate a valuation firm to assist in conducting" required IRO reviews. Valuation issues can be complex. Properly managing the fair market value determinations necessary to maintain compliance is at the heart of an effective Focus Arrangements Compliance Program.

Legal review of the arrangement is the third element of the review and approval process that is specifically required by this Focus Arrangements Procedure. For attorneys who are experienced in advising health care industry clients, the job of helping their clients align Focus Arrangements with the requirements of a Stark exception and/or anti-kickback safe harbor is almost second nature. As I have mentioned above in this article, the work of experienced health care attorneys in establishing Focus Arrangements is almost never the root cause of the compliance problems that I have seen and helped clients resolve in this important area of compliance risk.

Counseling clients on Stark and anti-kickback compliance, and structuring compliant arrangements, are probably not jobs that should be entrusted to even the best business or community attorney who does not have expertise in health care

legal requirements. These laws are technical and complex, and an understanding of related judicial precedent, and of what works in practice to assure compliance, are all important to providing reliable legal advice.

Creating and maintaining documentation that each arrangement has been reviewed by counsel is also important to the success of an Arrangements Compliance Program. This isn't rocket science, but it does require some precision to assure that, for example, the contract revision that is "reviewed and approved" by counsel is the contract revision that in the end is used by the organization to initiate an arrangement. The best model for documenting legal review that I have seen used the unique document number assigned to each draft or revision of documents by a legal department's document management system. The responsible attorney would simply transmit the final/approved document by email, with email text stating that "the attached contract, document number 'xxx,' has been reviewed and is approved as to legal form." The transmittal email was then scanned and uploaded into the organization's contract management system as evidence of legal review and approval of the contract in question.

While this Focus Arrangements Procedure does not specifically require management or board approvals of arrangements, most organizations will also have or develop required management approvals or board approvals for arrangements that would be Focus Arrangements in this CIA environment. These approvals often are linked to a contracting/spending authority that has been established by the organization for all different types of contractual arrangements (e.g., in many organizations all consulting or outside counsel agreements must be approved in advance by an organization's CEO or CFO, and all physician arrangements must have CEO or board approval), or tied to different spending levels (e.g., VPs have authority

up to \$100K; SVPs have authority up to \$250K; CEO and CFO have authority up to \$1M; and board must approve any contract over \$1M).

I have often seen procedures that require facility or regional CEO approval for any Focus Arrangement with a physician. It is also common to see board approval required for any physician compensation arrangement over a specified annual dollar amount, or over a specified threshold when compared with a specified physician compensation survey (e.g., "board must approval any physician arrangement where compensation will exceed the 75th percentile of compensation for physicians in the same or relevant specialty in the MGMA compensation survey data"). These management and board approvals are also essential to an effective Focus Arrangements Compliance Program, and documenting that each required approval occurred as required will be important to assuring that the defensive function of the compliance program can be relied upon to protect the organization from allegations of noncompliance.

The most effective Arrangements Compliance Programs clearly document the organization's review and approval requirements, and the procedures that have been adopted to complete required reviews and approvals, in one or more compliance policies; and responsible personnel throughout the organization (the "arrangements covered persons" in CIA parlance) are periodically trained on these requirements to facilitate a common understanding about what is required to meet organizational and legal requirements and to maintain compliance.

8. *"Ensuring that all existing Focus Arrangements are subject to the review and approval process described in [Section 7] above."*

This Focus Arrangements Procedures requirement that all existing Focus

Arrangements must also be (or have been) subject to the review and approval process established to meet requirement Focus Arrangements Procedure 7 immediately above was just added to the standard Focus Arrangements CIA form in 2018. Because I haven't already mentioned it elsewhere, it is worth noting here that Focus Arrangements CIA language has long required that Focus Arrangements Procedures must apply to *all new and renewed* Focus Arrangements. This means, if your organization is party to a Focus Arrangements CIA, when that medical director arrangement that was first instituted in 2002 auto-renews for the 15th time 20 days after the effective date of your new CIA, you need to have documentation of:

1. the business need or rationale for the arrangement,
2. the determination that the remuneration provided pursuant to the arrangement is fair market value,
3. legal review and approval of the arrangement, and
4. any management or board approvals that are required for the arrangement in question.

Because business needs, fair market value, and even the requirements of the Stark law and anti-kickback statute change from time to time, this documentation probably should, in most cases, happen in step with the renewal or auto-renewal process (documentation of business need or fair market value that is 15 years old will not, in most cases, protect the organization from allegations that the arrangement is no longer needed, or that the remuneration is not consistent with fair market value now). The application of this Focus Arrangements Procedures requirement to renewing arrangements also extends to the additional Focus Arrangements Requirements discussed below (these are additional requirements for each Focus Arrangement that must also now be met in existing Focus Arrangements).

The expansion of the review and approval requirements to *existing* arrangements simply means that a CIA-obligated organization can no longer wait five years (or maybe even one year) for an auto renewal to occur before assuring that every existing Focus Arrangement meets this Focus Arrangements Procedures requirement. Should an organization that is using the Focus Arrangements CIA as a model for establishing a voluntary Arrangements Compliance Program also extend the review and approval requirements to existing Focus Arrangements? Of course, the answer to this question is not a simple yes or no. For organizations that are not CIA-obligated, it may not be advisable, for example, to subject an existing arrangement that the organization is obligated to fulfill to board approval under a newly developed board approval process, but it might make sense to assure that the organization has current documentation that remuneration is at fair market value.

I have often told provider clients that, in my view (unlike in the claims development/billing and coding risk area) for an organization that is new to a structured process for assuring Stark and anti-kickback compliance, a random sample audit of physician arrangements is *not adequate* to provide assurance that there are no Focus Arrangements issues. If any single physician arrangement is not strictly adhering to the relevant Stark exception, *all of the resulting referred DHS for which the entity has billed and has been paid by Medicare becomes monies that the organization is not entitled to: It becomes an overpayment*. A single noncompliant physician arrangement could subject an organization to significant financial risk. Only a comprehensive review of physician arrangements can provide assurance that there are no significant lingering problems. In the same way, application of Focus Arrangements compliance requirements to all *new, renewing, and existing* arrangements is the best way to assure compliance.

9. *“Requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee.”*

An observation about this Focus Arrangements Procedures requirement: Here the CIA requires the compliance officer to review (*i.e.*, to audit/evaluate) the contract management system (FATS) and other Focus Arrangements Procedures on at least an annual basis. I doubt that the OIG would have inserted here a self-review requirement. Put another way—if the OIG believed that the compliance officer should be responsible for managing the contract management system (FATS) and other Focus Arrangements Procedures, then the OIG would likely have suggested here that someone else (internal audit or another independent internal or external reviewer) should review the contract management system and other Focus Arrangements Procedures. *The job of the compliance officer is to implement and operate the core elements of the organization's compliance program. The compliance officer should not also be responsible for the management tasks and roles for which the compliance program is intended to mitigate compliance risk.*

While the “fox watching the henhouse” adage doesn’t precisely capture the concern that placing a compliance officer in this kind of dual role creates (at least we hope this doesn’t accurately describe the problem), there is real value in a separation of roles when an organization is attempting to establish a working and effective compliance program. The compliance officer is responsible for managing the compliance program. Management is responsible for assuring compliance. Many of the requirements of the Focus Arrangements Procedures discussed in this article are tasks that others in an

organization (management, legal counsel) must complete. Managing the contract database, obtaining fair market value determinations, facilitating the contracting or approval processes—these are not the roles of the compliance officer. They are roles that belong to management of an organization.

Overseeing or conducting an auditing or monitoring function that is intended to confirm that management functions are operating as required by the organization's compliance requirements *does* fit squarely within the roles and responsibilities of an organizational compliance officer. If an organization has had significant challenges with Stark and anti-kickback compliance, an annual review of the procedures developed to promote and assure compliance in this area is probably not adequate to move the organization's compliance trajectory. I have often developed (or seen organizations develop) semi-annual or even quarterly reviews of a sample of Focus Arrangements to confirm on a more frequent basis that Focus Arrangements Procedures requirements are being adhered to. A less frequent (perhaps annual) review of the workings of the contract management system (FATS) may be appropriate once that system is established, but more frequent evaluations of the state of compliance with approval and other requirements is an effective way to assure that these requirements remain front-of-mind for responsible managers who are regularly required to comply with Focus Arrangements Procedures requirements.

10. *“Implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate.”*

Effective responses to suspected or discovered violations of the Stark law or

anti-kickback statute are also important to effective compliance. Understanding how these laws interact with the False Claims Act is key to establishing the right compliance process in a voluntary Arrangements Compliance Program. For CIA-obligated organizations, the CIA requires prescribed reporting to the OIG of “reportable events,” self-disclosure of “suspected” Stark violations to CMS, and report and return of any identified overpayments. The self-disclosure of Stark violations and report and return of identified overpayments requirements, however, may apply equally to organizations not subject to CIA requirements. Recall the Stark rule that is paraphrased above. When an entity bills Medicare (and is paid) for DHS referred by physician with whom the entity has a financial relationship that does not conform strictly to applicable Stark exception requirements, the entity has received funds it is not entitled to and is obligated by the Stark law to return. The entity is holding an overpayment. I have often seen organizations (I think rightly) conclude that they must either return these Medicare funds to the federal fisc or self-disclose the suspected noncompliance with Stark to CMS, to properly manage the risks posed by the False Claims Act when this occurs.

Ending the noncompliance (and the “period of disallowance”¹³ as defined by the Stark law) is also essential to limiting an organization’s exposure if a Stark compliance failure has occurred. It is also sometimes necessary, if an arrangement cannot quickly be brought back into compliance with an applicable exception, to initiate a “bill-hold” on billing for any resulting improper referrals. The anti-kickback statute brings with it similar risks if an instance of noncompliance is suspected or discovered. Assuring appropriate management and response when problems do arise is an important element of an effective Focus Arrangements Compliance Program. Appropriate corrective action,

remediation, and response measures in this area are essential to assuring that the “detection and correction” and “defense” strategies of an Arrangements Compliance Program operate to provide their fullest potential benefit to an organization that suspects or has discovered an instance of noncompliance.

ADDITIONAL FOCUS ARRANGEMENTS CONTRACTING REQUIREMENTS

In addition to the Focus Arrangements Procedures discussed above, Focus Arrangements CIAs have imposed the following contracting requirements on the Focus Arrangements themselves (and the parties to the Focus Arrangements).

- Ensure that all written Focus Arrangements each Focus Arrangement is set forth in writing and are signed by [the CIA obligated organization] and the other parties to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;
- ~~Include in the written agreement a requirement that each party to the Focus Arrangement who meets the definition of a covered person shall complete the arrangement training required by...this CIA. Additionally, [the CIA obligated party] shall provide each party to the Focus Arrangement with a copy of its code of conduct and Stark law and anti-kickback statute policies and procedures; and~~
- Ensure that all Focus Arrangements have been subject to the written review and approval process described in [Section 7 of this article] prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement, and that [the CIA obligated organization] maintains appropriate documentation of the review and approval of such Focus Arrangement; and
- Include in any written agreement a certification by the parties to the Focus Arrangement that the parties shall not

violate the anti-kickback statute and the Stark law with respect to the performance of the Arrangement.

As you can see, the Focus Arrangements requirements were amended in 2018 to remove a requirement that parties to the Focus Arrangement (*i.e.*, the physicians, physician organizations, and other suppliers) were required to complete the CIA-obligated organizations compliance training, and requiring the CIA-obligated organizations to distribute their Stark and anti-kickback policies and code of conduct to these parties. This change was likely a great relief to organizations entering CIAs, and it makes sense as often the training requirement was met by one individual on behalf of a contracted organization and has been of limited benefit. Organizations attempting to structure working and effective Arrangements Compliance Programs, however, should consider whether some physicians and others who are parties to Focus Arrangements should be required to complete the organization's arrangements-related specific compliance training. For example, a medical director who has been appointed to help with management of a unit may be in a position to create significant risk—or to help an organization avoid it—and may be a good candidate for contract language requiring annual training on the organization's arrangements compliance requirements.

Added to the Focus Arrangements requirements in 2018 is an obligation to assure that before payment or receipt of remuneration pursuant to any Focus Arrangements, the arrangement is (1) subject to the review and approval process, and (2) in writing (where required) and signed by the parties. These requirements are also both effective at limiting/eliminating risk for organizations not subject to a Focus Arrangements CIA, and most organizations with mature compliance processes have adopted similar requirements. In my experience a “no contract – no pay” policy is common for

organizations that are carefully managing their Focus Arrangements risks.

The third Focus Arrangements requirement—a certification that contracted parties will comply with the anti-kickback statute and Stark law in performing the arrangement—establishes the parties' intent to operate the arrangement in a compliant manner and adds grounds for termination of an arrangement where non-compliance is discovered. In my view, this also makes sense for an organization that is maintaining a voluntary Arrangements Compliance Program.

FOCUS ARRANGEMENTS CIA INDEPENDENT REVIEW ORGANIZATION (IRO) REQUIREMENTS

Delving deeply into the unique IRO requirements for Focus Arrangements CIAs is beyond the scope of this article, but IRO requirements in Focus Arrangements CIAs include (1) a “Systems Review” of the Focus Arrangements Tracking System and of other Focus Arrangements Procedures established by an organization, and (2) a “Transactions Review” of a randomly selected sample of Focus Arrangements to confirm compliance with the Focus Arrangements Procedures and Focus Arrangements Requirements.

Much has been written over the years about the importance of periodic independent audit: the value of having independent eyes evaluate various aspects of an organization's compliance and controls environment. An *annual* review of Focus Arrangements may be overkill or beyond the budget constraints of an organization that is not subject to CIA requirements. But, the basic model of a *periodic* review of (1) arrangements procedures, and (2) of a sample of Focus Arrangements by an outside/independent reviewer who is knowledgeable about the requirements of the Stark law and anti-kickback statute and who has experience establishing and/or evaluating compliance procedures in

this important risk area may make sense for any organization that is operating, and is committed to continuously improving, its voluntary Arrangements Compliance Program.

CONCLUSION

This article began with a question: Does the Focus Arrangements CIA provide a good model for an effective Stark and anti-kickback Compliance Program? I have worked with many organizations on their Arrangements Compliance Programs and processes—in nearly every capacity one could hold that has Focus Arrangements Compliance Program-related responsibilities. I have implemented and operated Arrangements Compliance Programs as a chief compliance officer; conducted structured evaluation of and made recommendations to improve existing Arrangements Compliance Programs as a consultant; assisted organizations as outside counsel with arrangement-related investigations and OIG or CMS self-disclosures; and served as IRO for organization's subject to a Focus Arrangements CIAs.

As I consider all that I have learned and experienced in each of these capacities, and as I think through each of the requirements outlined in current Focus Arrangements CIAs, my conclusion is that the current Focus Arrangements CIA form *does* provide a good model for organizations that are seeking to establish or evaluate and improve their voluntary Arrangements Compliance Program. While each organization is unique in size, in how it operates, and in the risk profile that its operations create, the basic outline of operational and compliance processes found in CIA Focus Arrangements Procedures and Requirements should be evaluated and considered for implementation by any organization seeking to

operate an effective Focus Arrangements Compliance Program.

Endnotes

1. I'll refer to compliance programs that are focused on Stark and anti-kickback-related risks—rather, they are entered voluntarily or as the result of CIA requirements—as “Arrangements Compliance Programs” throughout. Where I use the terms “Focus Arrangements” I'll be referring specifically to requirements of a Focus Arrangements CIA.
2. DOJ's Justice Manual §9-28.300, www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations
3. DOJ *Evaluation of Corporate Compliance Programs* at page 2, www.justice.gov/criminal-fraud/page/file/937501/download
4. *2018 Healthcare Compliance Benchmark Report*, SAI Global and Strategic Management Services.
5. 42 U.S.C. § 1320a-7b
6. 42 U.S.C. § 1325nn
7. 42 C.F.R. §§ 411.355, 411.356, 411.357
8. The terms that are in bold type here are each defined specifically in the Stark law and regulations. Explaining these definitions and providing a more in-depth discussion of the requirements of the Stark law or anti-kickback statute are beyond the scope of this article.
9. oig.hhs.gov/fraud/cia/agreements/TenetCIAFinal.pdf
10. In this way, arrangements that satisfy the requirements of 42 C.F.R. §§411.356 (ownership or investment interests); 411.357(g); (remuneration unrelated to the provision of designated health services); 411.357(i) (payment by a physician for items and services); 411.357(k) (non-monetary compensation); 411.357(m) (medical staff incidental benefits); 411.357(o) (compliance training); 411.357(q) (referral services); 411.357(s) (professional courtesy); or 357(u) (community-wide health information systems) are not considered “Focus Arrangements,” and are not subject to the CIA's compliance requirements.
11. oig.hhs.gov/fraud/cia/agreements/Halifax_Hospital_03102014.pdf
12. oig.hhs.gov/fraud/cia/agreements/William_Beaumont_Hospital_07312018.pdf
13. The Stark law generally defines the “period of disallowance” as the period during which the arrangement has failed to comply with an applicable exception and, because of the noncompliance, the period during which the physician's referrals of DHS are prohibited, and during which the entity may not bill Medicare for improperly referred DHS.

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