Contracting with Physicians or Other Referral Sources

By Linda A. Baumann and Samuel C. Cohen

Arent Fox LLP
I. Introduction ................................................................................................................... 1

II. The Enforcement Landscape ......................................................................................... 1
   A. Basis for Government Restrictions on Financial Arrangements with Referral Sources .................................................. 1
   B. Health Care Contracting Has Unique Requirements ................................................................ 2
   C. Referral Sources ................................................................................................ 2
   D. Overview of Applicable Laws ............................................................................. 2
      i. Federal Physician Self-Referral Law (“Stark Law”) ............................................... 2
      ii. Federal Anti-Kickback Statute ........................................................................ 3
      iii. Other Federal Health Care Statutes .................................................................. 4
      iv. State Laws ........................................................................................................ 4
   E. Substantial Exposure for Failure to Comply ....................................................... 4
      i. False Claims Act .......................................................................................... 4
      ii. Civil Monetary Penalties .............................................................................. 5
      iii. Exclusion ....................................................................................................... 5

III. Negotiating Agreements ................................................................................................ 6
   A. Identify the Type of Arrangement At Issue ......................................................... 5
      i. Ownership/Investment Interests ..................................................................... 6
      ii. Compensation Arrangements ........................................................................ 6
   B. Contracting for an Appropriate Reason .............................................................. 7
   C. Contracting with an Appropriate Individual or Entity ........................................... 7
   D. Timing and Framework for Contract Negotiations .............................................. 8
      i. All Parties Should Sign the Contract Before the Effective Date ............... 8
      ii. Evaluate All Services the Parties will Provide under All Agreements .......................................................... 8
      iii. Certain Payment Methodologies Can Create Additional Exposure ......... 8
   E. Written Agreements Provide the Greatest Protection ......................................... 9
   F. Common Requirements for Permissible Financial Arrangements ....................... 9
      i. Signed, Written Agreement ........................................................................... 9
      ii. Contract Should Specify All Services and Items Covered .......................... 10
      iii. Term of at Least One Year .......................................................................... 10
      iv. Commercially Reasonable Terms ................................................................ 10
      v. Fair Market Value Compensation ................................................................. 10
Table of Contents
(continued)

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>G. Documenting Fair Market Value and Commercial Reasonableness</td>
<td>11</td>
</tr>
<tr>
<td>i. Methods for Determining Fair Market Value and Commercial Reasonableness</td>
<td>11</td>
</tr>
<tr>
<td>ii. Best Practices</td>
<td>11</td>
</tr>
<tr>
<td>IV. Implementing and Monitoring Contracts with Referral Sources</td>
<td>12</td>
</tr>
<tr>
<td>A. Evaluate the Continued Need for the Services</td>
<td>12</td>
</tr>
<tr>
<td>B. Confirm that the Correct Items or Services are Actually Being Provided</td>
<td>13</td>
</tr>
<tr>
<td>C. Monitor for Quality and Other Issues Related to the Services Provided</td>
<td>13</td>
</tr>
<tr>
<td>D. Enforce the Terms of the Agreement</td>
<td>13</td>
</tr>
<tr>
<td>E. Renew Agreements in a Timely Manner</td>
<td>14</td>
</tr>
<tr>
<td>V. Conclusion</td>
<td>14</td>
</tr>
</tbody>
</table>
I. Introduction

The federal government has enacted many laws governing financial arrangements with physicians and other individuals and entities that refer patients for items or services or other business that may be paid for by a federal or state health care program. As a result, negotiating and executing financial arrangements with physicians or other referral sources can create substantial exposure for companies doing business in the health care industry. Failure to comply with the often nuanced requirements of applicable law can lead to substantial fines and penalties or other, even more serious repercussions, such as exclusion from participation in federal health care programs, as well as criminal prosecution. At the same time, it frequently is necessary to enter into at least some financial arrangements with referral sources.

The situation is further complicated because health law is unique in several respects and conduct that is permissible in other industries can violate federal and state law in the context of the health care industry. This chapter is designed to help in-house counsel understand the general legal environment by providing practical guidance on a number of key issues related to contracting with physicians and other referral sources. This chapter does not, however, provide specific legal advice. Many of the applicable requirements (particularly under the Stark law) are extremely complex and/or ambiguous. Attorneys who do not focus on health law often are not aware of the unique restrictions applicable to the health care industry. Accordingly, in-house counsel may well find it advisable to consult experienced health care attorneys before negotiating an agreement with a physician or other referral source.

II. The Enforcement Landscape

A. Basis for Government Restrictions on Financial Arrangements with Referral Sources

Health care businesses generally rely heavily on referrals from physicians and other referral sources. These referrals can come in many forms, such as a referral of a patient to a hospital emergency room, nursing home, or home health agency or an order for a particular item, such as a specific type of urological supply or a pharmaceutical. The receipt of a referral generally provides a health care business with the opportunity to receive revenue by billing third-party payors, including the government, for the items or services provided pursuant to the referral.

The federal government historically has been concerned that businesses might offer improper financial incentives for referrals to physicians and other referral sources and that these incentives potentially could lead to an overutilization of health care services. The federal government’s concern arises both from its status as the largest payor for health care services in the country and from its concern that inappropriate financial incentives can corrupt medical decision-making, resulting in harm to patients. To address these concerns, the government has enacted various laws, often referred to as
the “fraud and abuse laws,” to prevent physicians and other referral sources from receiving financial incentives for referring patients or business.

**B. Health Care Contracting Has Unique Requirements**

The fraud and abuse laws create restrictions unique to the health care industry, and in many cases they can create liability for business practices that are acceptable (and common) in other industries. Because the level of enforcement and the potential penalties are so much greater when the government is involved, this chapter will focus on contractual relationships that involve one of the parties ultimately billing a government health care program for the items or services acquired through the contractual relationship.1

**C. Referral Sources**

For purposes of this chapter, “referral sources” are those individuals or entities that may refer patients or other business to another individual or entity that will bill a government health care program for these items or services. A referral source obviously includes those physicians who may refer patients to a particular business. However, as described in more detail below, contracting with certain family members of a physician (as broadly defined in the Stark law) will be treated the same way as contracting with the referring physician.

In addition, depending on the circumstances, a referral source may include a much broader range of entities, such as: (i) a nursing home or home health agency that refers Medicare or Medicaid patients to a hospital; (ii) a drug or device company that sells items to a hospital or nursing home that will bill Medicare or Medicaid for these items; and (iii) individuals or entities hired to provide marketing services or set up managed care networks for entities that will bill Medicare, Medicaid, or other federal health care programs.

**D. Overview of Applicable Laws**

A few key laws and their main provisions are noted below.

i. **Federal Physician Self-Referral Law (“Stark Law”)**

The Physician Self-Referral Law, generally referred to as the Stark law,2 is a strict liability statute that prohibits physicians from referring Medicare3 patients to an entity for the furnishing of certain “designated health services” if the physician (or an immediate family member4) has a financial relationship with the entity, unless an exception applies.5 An entity also may not bill Medicare (or any other individual or entity) for services furnished pursuant to a prohibited referral.6

Exceptions exist for many types of financial relationships with physicians, and most of these exceptions require that the arrangements: (i) have compensation that is fair market value and does not take into account (directly or indirectly) the volume or value of referrals between the parties, and (ii) be commercially reasonable,7 in addition to
meeting various other criteria. Because the Stark law is a strict liability statute, once the statute is implicated, the financial relationship must meet all of the requirements of an appropriate exception. A list of Stark law exceptions is included as Appendix A to this chapter.

Penalties for Stark law violations include denial of claims for improperly referred “designated health services,”8 required repayment of amounts received from Medicare and from patients, and the imposition of civil monetary penalties. These financial penalties can be severe since they do not relate to the amount of improper remuneration provided to the physician (or their family member); rather, the damages relate to all the reimbursement received from Medicare for referrals made by the physician at issue while an improper financial relationship existed. Stark law violations also can serve as the basis for False Claims Act liability (discussed below). In addition, Stark law violations can result in exclusion from participation in federal health care programs, which is commonly considered a “financial death sentence.” Typically, if the Stark law is implicated, compliance with the anti-kickback statute also will be necessary. The two statutes have overlapping, but not identical, requirements.

ii. Federal Anti-Kickback Statute

The federal anti-kickback statute prohibits knowingly and willfully soliciting, receiving, offering, or paying any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) to induce or reward referrals of patients, items, or services that may be paid for under a federal health care program, including, but not limited to, Medicare, Medicaid, or TriCare.9 The statute applies to both sides of an impermissible “kickback” transaction, and the statute has been interpreted by numerous courts to apply to any arrangement where even “one purpose” of the remuneration is to induce or reward referrals.10

The anti-kickback statute and accompanying regulations include safe harbors that generally immunize arrangements that meet all the conditions of the safe harbor from prosecution.11 All of the requirements of a safe harbor must be met in order to receive its protection. However, because the anti-kickback statute is an intent-based statute, failure to fully satisfy a safe harbor does not constitute a per se violation of the law. A list of anti-kickback statute safe harbors is included as Appendix B to this chapter.

Anti-kickback statute violations can result in criminal fines of up to $25,000 and/or up to five years imprisonment per violation. Violations also can result in civil monetary penalties of up to $50,000 per violation and damages of up to three times the amount of the illegal kickback and may serve as the basis for False Claims Act liability, as well as result in exclusion from participation in federal health care programs. When a referral source other than a physician is involved, the focus will be on compliance with the anti-kickback statute because the Stark law will not be implicated when a physician is not involved.
iii. Other Federal Health Care Statutes

While the Stark law and the anti-kickback statute are two of the key federal statutes governing financial relationships with referral sources, the federal government also has passed a number of other health laws potentially applicable to these relationships. As an example, the criminal health care fraud statute prohibits individuals from knowingly and willfully executing, or attempting to execute, a scheme to defraud a health care program or to obtain by false or fraudulent pretenses money or property under the custody or control of a health care program in connection with the delivery of or payment for health care benefits, items, or services. Another similar statute prohibits actions such as knowingly and willfully falsifying or concealing a material fact, making materially false statements, or making or using any materially false document (knowing that it contains false information) in matters involving the delivery of or payment for health care benefits, items, or services. Some of these statutes are applicable to all payors, not just certain government health care programs.

iv. State Laws

Although the federal statutes described above have the most far-reaching applicability, in-house counsel also should be cognizant of applicable state law restrictions when entering into negotiations with physicians and other referral sources. For example, in many cases, states also have their own physician self-referral laws, anti-kickback statutes, and fee-splitting prohibitions. These laws can be both broader and narrower than their federal counterparts. Some state laws may be limited to actions affecting only the Medicaid program, but many state laws apply to all payors. States also may have consumer protection or other types of laws that are not limited to health care programs but may be used in that context.

E. Substantial Exposure for Failure to Comply

Health care fraud enforcement has increased steadily over the last ten to fifteen years, and this trend has increased with the passage of the Affordable Care Act in 2010. Thus, health care businesses that fail to comply with the requirements of the various statutes described above when negotiating and implementing financial arrangements with physicians or other referral sources can expose themselves to substantial liability. A few of the key enforcement provisions are described below.

i. False Claims Act

The federal False Claims Act prohibits, among other activities, knowingly presenting or causing to be presented a false or fraudulent claim for payment by a federal health care program. Notably, claims submitted to federal health care programs in violation of the Stark law or the anti-kickback statute can result in False Claims Act liability. Stark law cases in particular are frequently enforced through the False Claims Act because the Stark law imposes strict liability.

Violations of the False Claims Act can result in the imposition of treble damages and civil monetary penalties of between $5,500 and $11,000 per claim. Because health care
businesses often submit a substantial number of claims, the civil monetary penalties associated with the False Claims Act can be very large and may exceed the applicable damages in certain cases. Businesses also can be excluded from participation in federal health care programs for violations of the False Claims Act.

Moreover, the False Claims Act allows a private individual (referred to as a qui tam relator or “whistleblower”) to enforce the Act by filing a sealed complaint alleging fraud against the government. Whistleblowers have tremendous incentive to bring False Claims Act cases, as they can receive up to 30 percent of the government’s recoveries, as well as their attorneys’ fees.\(^{14}\)

**ii. Civil Monetary Penalties**

The Department of Health and Human Services Office of Inspector General (“OIG”) can impose civil monetary penalties for various specified actions, including (i) violating the anti-kickback statute; (ii) violating the Stark law; (iii) presenting false or improper claims; (iv) offering remuneration to a beneficiary to influence the beneficiary’s decision-making (referred to as “beneficiary inducement”); (v) presenting a claim or ordering services for which a claim will be made to a federal health care program while excluded from participation in federal health care programs; and (vi) providing payments to a physician to induce the physician to limit or reduce services provided to a patient.\(^{15}\) In most cases, the OIG can impose civil monetary penalties of up to $10,000 per item or service, although in certain cases the OIG is authorized to impose civil monetary penalties of up to $50,000 per act. Treble damages also may be imposed.\(^{16}\) Persons or entities that are subject to civil monetary penalties also may be subject to exclusion from federal health care programs.

**iii. Exclusion**

The OIG is authorized to exclude individuals and entities from participation in federal health care programs. As noted above, exclusion is an extremely serious sanction. Exclusion is mandatory in some circumstances, such as for individuals or entities convicted of certain health care-related offenses,\(^{17}\) and mandatory exclusion will be for at least a five year period.\(^{18}\) The OIG also has permissive (discretionary) authority to exclude individuals or entities who engage in various types of prohibited conduct, including: (i) certain convictions related to fraud; (ii) obstruction of an investigation; (iii) claims for excessive charges and unnecessary services; and (iv) fraud, kickbacks, and other prohibited activities. Permissive exclusion also may be imposed on entities controlled by a sanctioned individual and on individuals controlling a sanctioned entity.\(^{19}\)

The OIG interprets its exclusion authority very broadly and has stated that no federal program payments may be made for any items or services furnished by an excluded person or at the medical direction or on the prescription of an excluded person, even if the excluded person does not provide direct patient care or the items or services provided by the excluded individual are billed separately. Thus, according to the OIG, no practitioner, provider, or supplier can employ or contract with an excluded individual or entity to furnish any items or services reimbursed by a federal health care program.\(^{20}\)
To avoid running afoul of these legal requirements, businesses involved in the health care industry should carefully check the names of their employees and contractors against the OIG’s List of Excluded Individuals/Entities (LEIE) and the list maintained by the System for Award Management (“SAM”). The OIG recommends using the LEIE as the primary source of information about OIG exclusions, although businesses also should check the SAM to ensure that employees and contractors have not been the subject of debarment actions taken by other federal agencies. Guidance for in-house counsel on how to check an individual’s exclusion status using the LEIE is included in Appendix C to this chapter.

III. Negotiating Agreements

A. Identify the Type of Arrangement At Issue

Health care businesses may enter into many different types of financial arrangements with physicians and other referrals sources, and the applicable legal requirements may vary depending on the type of arrangement at issue.

i. Ownership/Investment Interests

Potential financial arrangements include those involving direct or indirect ownership interests, including stock ownership or options, joint ventures, secured loans, and even unsecured loans in certain cases. Since many arrangements involving ownership by a physician in an entity to which the physician will refer business are prohibited by the Stark law, any proposed arrangement involving an ownership or investment interest by a physician or a member of the physician’s family should be very closely scrutinized. Even when physicians are not involved, businesses always should ensure compliance with the anti-kickback statute, e.g., making sure that referral sources are only offered ownership interests on the same terms that ownership interests would be offered to those who do not make referrals to the business.

ii. Compensation Arrangements

Most potential arrangements with physicians (and their immediate family members) and other referral sources involve compensation arrangements. These compensation arrangements can come in a variety of forms, including medical director agreements, clinical services arrangements such as providing call coverage, space or equipment leases, marketing or management arrangements, and the sale or purchase of any type of asset. Importantly, compensation arrangements should be monitored for compliance with the fraud and abuse laws regardless of whether the physician or other referral source is the buyer, seller, lessor, or lessee. Compensation arrangements also include indirect compensation arrangements, so health care businesses should pay close attention to the entities with which they are contracting to ensure that they do not accidentally create exposure by entering into an impermissible indirect compensation arrangement.

The Stark law includes a unique and complex definition of an indirect compensation arrangement. The process for determining whether an indirect compensation
arrangement exists under this definition is outlined in the chart included as Appendix D to this chapter. Because the requirements for the exceptions applicable to direct and indirect financial arrangements differ, health care businesses carefully should consider whether there are advantages to contracting with a physician’s group practice or other entity instead of with the physician as an individual.

*In addition to various other criteria, depending on the exact type of arrangement at issue, almost every compensation arrangement with a referral source should be commercially reasonable and have compensation that is fair market value and does not reflect the referral of patients or other business between the parties.*

**B. Contracting for an Appropriate Reason**

The first step when considering whether to enter into a financial arrangement with a physician or other referral source is confirming that the arrangement is being entered into for an appropriate reason, i.e., that there is a bona fide, commercially reasonable business purpose behind the arrangement. The arrangement should make sense even if the physician or other referral source made no referrals to the business with which they are contracting.

**C. Contracting with an Appropriate Individual or Entity**

Once it has been determined that there is an appropriate business purpose for the arrangement, health care businesses should make sure that they are contracting with the “right” person for the “right job.” It is essential to ensure that the physician or other referral source is both qualified and eligible to provide the desired services. At a minimum, a health care business should confirm that the physician or other referral source has valid, current licenses, if required to provide the items or services, and that the individual or entity is not excluded from participation in federal health care programs. (See Appendix C to this chapter.)

In addition, a health care business generally should not pay a physician (at a physician’s salary) for services that could be provided by a nurse. (If a physician is being paid physician-level compensation to perform services that do not require a physician’s skill or knowledge, the government likely will believe that the payments are being made, at least in part, to induce referrals from the physician.) Further, the government will expect a cardiothoracic surgeon to be paid far less for providing administrative services, such as medical director duties, than what the surgeon might be paid for performing open-heart surgery. Thus, businesses should do their utmost to ensure a good fit between the skills needed to perform a job and the person hired (and the salary paid) to do the job.

Finally, businesses should consider whether it is more appropriate to contract with a physician or the physician’s practice group, or other entity if applicable. Considerations in making this decision should include logistical factors, e.g., is a single physician capable of providing all of the necessary services. In addition, this decision also should
include an analysis of the potentially different restrictions applicable to direct and indirect compensation arrangements with physicians, as discussed above.

D. Timing and Framework for Contract Negotiations

i. All Parties Should Sign the Contract Before the Effective Date

This is an area where health law, specifically the Stark law, creates unique restrictions. Negotiations with an appropriate physician or other referral source should start early enough so that there is sufficient time to fully negotiate and execute the agreement before the required services need to be performed. While it is always a good practice to have a fully executed agreement in place before services are provided, having a written agreement in place, and signed by all parties, before any items or services are provided is essential when the contract involves a physician (or their immediate family member) in order to achieve compliance with certain Stark Law exceptions. While there are some limited exceptions to this rule, and regardless of whether state law allows a contract to have a retroactive effective date, a business substantially increases its exposure if it does not regularly have fully-executed agreements in place before items or services are furnished.

ii. Evaluate All Services the Parties will Provide under All Agreements

As part of preparing for and engaging in negotiations with a physician, their immediate family member, or other referral source, a health care business also should be aware of any other potentially relevant agreements with these parties. First, the very commonly used Stark law exception for personal services arrangements requires that all such contracts incorporate each other or cross reference a master list. However, even when a physician (and the Stark law) is not involved, businesses should evaluate whether multiple financial arrangements with referral sources are commercially reasonable, individually and in the aggregate. In other words, if the total amount of services being contracted for under all the agreements are not reasonably necessary to accomplish a legitimate business purpose (or if it is not plausible that the physician or other referral source could provide the aggregate amount of services), then the new agreement should not be executed, even if the new agreement is reasonable when analyzed in isolation.

iii. Certain Payment Methodologies Can Create Additional Exposure

Payment methodologies can be an important consideration when negotiating agreements with physicians and other referral sources. Percentage compensation should be carefully structured to reduce the risk that compensation will be viewed as payment for referrals. The government has indicated that percentage compensation is particularly suspect as a means of payment for marketing or billing arrangements and thus, while common in the industry, percentage compensation for any such arrangements is best to avoid if at all possible. However, if a business decides that it needs to use percentage compensation in a contract for these types of services, using a “safeguard,” such as setting a cap on overall compensation, may help reduce the risk.
In addition, it is essential to comply with the special rules for “per click” or “per unit of time” compensation when a physician (or their immediate family member) and the Stark law is involved.

**E. Written Agreements Provide the Greatest Protection**

Once a financial arrangement with a physician or other referral source has been successfully negotiated, it is important to ensure that the arrangement is documented appropriately. Many Stark law exceptions require a written agreement that meets all criteria in the applicable exception. While there are a few situations where written agreements are not required, compliance best practices indicate that written agreements can be extremely important in demonstrating that the arrangement is, in fact, compliant.

Because the Stark law is a strict liability statute, all financial arrangements with a physician or a physician’s immediate family member must meet the requirements of a Stark law exception if the law is implicated. As a result, it is essential that all of the criteria for an applicable exception are satisfied since even “technical” violations can lead to substantial liability. At the same time, all financial arrangements with physicians and other referral sources should be structured to the extent possible to comply with all the requirements of an applicable safe harbor to the anti-kickback statute. Because the anti-kickback statute is an intent-based statute, safe harbor compliance is advisable but not legally required. Nevertheless, if the arrangement does not satisfy all the criteria in a safe harbor, it will be necessary to demonstrate that the arrangement does not violate the language of the anti-kickback statute itself. A written agreement that satisfies as many safe harbor criteria as possible is one of the best ways to demonstrate compliance.

**F. Common Requirements for Permissible Financial Arrangements**

The Stark law exceptions and anti-kickback statute safe harbors vary depending on the type of arrangement at issue. While each exception and safe harbor has specific (and often unique) criteria, many of the exceptions and safe harbors include common requirements. Some of the more common requirements are noted below.

1. **Signed, Written Agreement**

Arrangements generally should be memorialized in a written agreement signed by the parties. As noted above, particularly when the Stark law is involved, the agreement should be signed by the parties before the effective date of the agreement, i.e., before any service is provided or any compensation is paid. The few exceptions to this requirement often are limited, e.g., the agreement still must be signed within a short time period after its effective date to qualify for the exception, and the exception can be used only once every three years for the same physician.
ii. Contract Should Specify All Services and Items Covered

Agreements with physicians and other referral sources should specify all of the services and items covered by arrangements between the parties. If a business has more than one financial arrangement with a physician or other referral source, each agreement generally should incorporate the other applicable arrangements or cross-reference a master list of contracts. It can be particularly important to update the description of items and services provided as they may change over time.

iii. Term of at Least One Year

Most Stark law exceptions and anti-kickback statute safe harbors require financial arrangements to have a term of at least one year. Arrangements of less than one year are permitted under some circumstances, but arrangements lasting less than one year generally must comply with additional requirements.

iv. Commercially Reasonable Terms

Compensation arrangements generally should have terms that are commercially reasonable even in the absence of any referrals between the parties to the agreement. However, the term “commercially reasonable” is not defined in the Stark law or regulations or by the anti-kickback statute, and there is very little available guidance as to how the phrase should be interpreted. Generally, the contract terms should be similar to those that would apply if the contract did not involve a referral source. For example, a business should not offer to loan money to a referral source for 10 years, if a bank likely would loan the money only for a 3 year period. There also are indications that the government believes a contract to employ a physician is only commercially reasonable if the employer will make a profit (or come very close to it) on the physician’s professional fees alone.

v. Fair Market Value Compensation

Compensation arrangements should include fair market value compensation, which generally refers to the compensation that would be paid as the result of arm’s-length negotiations between parties who are not otherwise in a position to generate business for each other. Fair market value compensation also generally should be set in advance. Depending on the circumstances, this standard can require either that the aggregate compensation should be set in advance or that the compensation methodology should be set in advance. Fair market value compensation generally should be determined in a manner that does not take into account the volume or value of referrals or other business generated between the parties.

G. Documenting Fair Market Value and Commercial Reasonableness

It is particularly important that contract files include documentation that financial arrangements with physicians and other referrals sources involve fair market value compensation and are commercially reasonable. Notably, the government has frequently challenged internal and even external determinations that an arrangement is
fair market value and/or commercially reasonable when these arrangements have become the subject of scrutiny. Thus, while maintaining files with documentation on these issues does not eliminate all risk, having these files may significantly reduce the potential exposure.

   i. Methods for Determining Fair Market Value and Commercial Reasonableness

Fair market value compensation and the commercial reasonableness of financial arrangements can be demonstrated in a variety of ways although, as noted above, none are exempt from government scrutiny and challenge. The Centers for Medicare and Medicaid Services ("CMS"), the agency charged with interpretation of the Stark Law, has said that for the purposes of establishing fair market value, it will accept any method that is commercially reasonable and provides evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue by parties in arm’s-length transactions who are not in a position to refer to one another. Examples of methods that might be acceptable for establishing fair market value, depending on the circumstances, include attestations from the other party, consulting a price list, analyzing a list of comparable properties and/or transactions, calculating a reasonable rate of return on an investment, following Internal Revenue Service guidelines on fair market value for tax-exempt organizations, using internally generated surveys or independently published salary surveys, and receiving an opinion from a qualified independent expert.21 Similarly, CMS has said that any reasonable method of valuation is acceptable for determining whether a transaction is commercially reasonable, so long as the determination is based on the specific business in which the parties are involved, not business in general.22 CMS has not, however, provided examples of methods that might be used in making a commercial reasonableness determination, although it did state that parties could request an advisory opinion for difficult cases.23

   ii. Best Practices

While no specific methodology or documentation is required, as a best practice, businesses should consider obtaining a fair market value and commercial reasonableness determination from a qualified independent expert, especially when the financial arrangement involves high compensation. Relying on a determination made by an independent expert can provide additional credibility and protection if the government decides to scrutinize a financial arrangement. In addition, reliance on an outside expert helps demonstrate the health care business’ intent to comply with the law.

For financial arrangements involving moderate (or low) compensation, it may be appropriate for health care businesses to rely on internally completed fair market value and commercial reasonableness determinations. Fair market value compensation can be determined by reference to independently published salary surveys. If possible, multiple salary surveys should be consulted, and health care businesses should make sure that proposed compensation is being compared to the appropriate survey data,
e.g., salaries for employed versus non-employed physicians, clinical versus administrative services, correct specialty, applicable geographic region, etc.

Regardless of the method used to determine fair market value and commercial reasonableness, the determination should be individualized and clearly state the rationales supporting the determination. It is important to maintain contemporaneous documentation supporting the final determination in the applicable files.

It also is a best practice to review all fair market value and commercial reasonableness determinations every two or three years. Therefore, longer agreements with physicians or other referral sources should include provisions allowing for the agreement to be amended or terminated if it is no longer consistent with fair market value or commercially reasonable at that time.

Finally, while multiple assessments (e.g., from different independent experts) can be helpful under certain circumstances, it is important not to appear to be "forum shopping" for an expert opinion that will support a higher level of compensation.

IV. Implementing and Monitoring Contracts with Referral Sources

Successfully negotiating and executing a financial arrangement with a physician or other referral source does not eliminate all potential risk. Indeed, many such contracts are successfully executed, but then lead to substantial exposure due to improper implementation. To avoid this risk, auditing and monitoring systems should be established to properly monitor implementation of these contracts. As an initial step in this process, policies and procedures should be issued to help track all financial arrangements with referral sources to ensure that no arrangements fall out of compliance because they have “slipped through the cracks.”

A few of the most common compliance issues related to improper contract implementation are noted below.

A. Evaluate the Continued Need for the Services

Business needs often evolve over time. While certain items or services might have been required at the time an agreement was signed originally, they might no longer be needed as time passes. For example, it is important to periodically confirm that the physician’s or other referral source’s services are still required and take steps to modify or terminate the agreement if the services are no longer necessary, in whole or in part. At a minimum, this evaluation should be performed before any agreement is renewed for an additional term. (Towards this end, businesses may want to consider whether it is appropriate to have automatic renewal provisions in contracts with referral sources.)

B. Confirm that the Correct Items or Services are Actually Being Provided

It is equally important to make sure that physicians and other referrals sources actually are providing the items or services called for by their contracts. If some or all of the items or services are not being provided, the government may view the agreements as
providing excess compensation to the referral source in exchange for referrals. Referral sources should be required to fill out time logs with entries sufficiently detailed to allow verification that the listed services were performed. Time logs should be reviewed and approved by appropriate personnel before payments are made for the services.

Similarly, referral sources should not be permitted to use more items or services than permitted by the relevant agreement. For example, if a business is leasing 100 square feet of office space to a referral source, the business should periodically check to be sure that the referral source is not using any part of the closet or suite next door. In the same vein, if the lease involves the use of two parking spaces, the referral source should not be allowed to use four spaces.

C. Monitor for Quality and Other Issues Related to the Services Provided

Another key part of contract oversight is to monitor implementation to be sure that the quality of the furnished items or services is consistent with relevant standards. For example, physicians providing medical services should be periodically audited to ensure that there are no coding, billing, or medical necessity issues with the services being provided. Paying a physician or other referral source at market rates for substandard services may not be considered consistent with fair market value. Similarly, if a physician or other referral source is being paid on a productivity basis, then over-coding by the physician may result in providing the physician with excessive compensation, i.e., more than is appropriate based on the services actually provided. In addition, over-coding by a physician and other quality issues also may expose a health care business to serious additional liability not directly related to the terms of the financial arrangement with the physician.

D. Enforce the Terms of the Agreement

Financial arrangements with physicians or other referral sources may include provisions that alter compensation or other contract requirements if certain events occur. For example, many lease agreements require the payment of late fees if rent is not received within a specified time period. In other cases, a contract may require a physician's compensation to be reduced if certain productivity targets are not met. Required payments should be collected as required, and other relevant provisions also should be properly implemented. Failure to enforce these provisions may result in the compensation no longer being consistent with fair market value or the agreement no longer being considered commercially reasonable.

E. Renew Agreements in a Timely Manner

As discussed above, contracts with a physician or other referral source should be signed before any services are provided or any compensation is paid. After an initial agreement has been executed and implemented, the parties may want to continue the financial arrangement beyond the term of the initial agreement. In these cases, the renewal agreement or extension to the underlying agreement should be signed before the expiration of the term of the initial agreement to ensure that no services are
provided (and no compensation is paid) without a signed, written agreement being in place. There are some circumstances in which payments may be made for services provided after an initial agreement has ended and before a new agreement is executed. However, because these circumstances are fairly limited, in-house counsel should consult with experienced health care attorneys before trying to rely on one of the exceptions.

V. Conclusion

Companies doing business in the health care industry must grapple with a vast array of laws governing their financial arrangements with physicians and other referral sources. Complying with these laws significantly increases the difficulty and time required to negotiate and execute financial arrangements with referral sources. However, failure to comply with these laws can create substantial liability, including fines, penalties, exclusion from participation in federal health care programs, and criminal prosecution. In many cases, these risks apply to both parties to the transaction. These laws often have complex, unique requirements, and in some cases even accidental violations of the law can result in liability. Based on these considerations, businesses may find it prudent to implement policies and procedures that go "above and beyond" the minimum legal requirements in order to reduce the risk of exposure.

This chapter has provided an overview of the general legal environment surrounding contracting with physicians and other referral sources. However, due to the unique nature of the laws and regulations in this context, in-house counsel should consider consulting an experienced health care attorney if any questions should arise.
## Stark Law Exceptions

<table>
<thead>
<tr>
<th>Ownership/Investment &amp; Compensation</th>
<th>Ownership or Investment Interests</th>
<th>Compensation Arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Physician Services</td>
<td>• Publicly-traded securities</td>
<td>• Rental of office space</td>
</tr>
<tr>
<td>• In-office ancillary services</td>
<td>• Mutual funds</td>
<td>• Rental of equipment</td>
</tr>
<tr>
<td>• Services furnished by an organization to enrollees</td>
<td>• Specific providers</td>
<td>• Bona fide employment relationships</td>
</tr>
<tr>
<td>• Academic medical centers</td>
<td>o Rural provider</td>
<td>• Personal service arrangements</td>
</tr>
<tr>
<td>• Implants furnished by an ASC</td>
<td>o Hospital in Puerto Rico</td>
<td>• Physician recruitment</td>
</tr>
<tr>
<td>• EPO and other dialysis-related drugs</td>
<td></td>
<td>• Isolated transactions</td>
</tr>
<tr>
<td>• Preventive screening tests, immunizations, and vaccines</td>
<td>o Whole hospital</td>
<td>• Certain arrangements with hospitals</td>
</tr>
<tr>
<td>• Eyeglasses and contact lenses following cataract surgery</td>
<td></td>
<td>• Group practice arrangements with a hospital</td>
</tr>
<tr>
<td>• Intra-family rural referrals</td>
<td></td>
<td>• Payments by a physician</td>
</tr>
<tr>
<td>• Publicly-traded securities</td>
<td></td>
<td>• Charitable donations by a physician</td>
</tr>
<tr>
<td>• Mutual funds</td>
<td></td>
<td>• Nonmonetary compensation</td>
</tr>
<tr>
<td>• Specific providers</td>
<td></td>
<td>• Fair market value</td>
</tr>
<tr>
<td>• Publicly-traded securities</td>
<td></td>
<td>• Medical staff incidental</td>
</tr>
<tr>
<td>• Mutual funds</td>
<td></td>
<td>• benefits</td>
</tr>
<tr>
<td>• Specific providers</td>
<td></td>
<td>• Risk-sharing arrangements</td>
</tr>
<tr>
<td>• Publicly-traded securities</td>
<td></td>
<td>• Compliance training</td>
</tr>
<tr>
<td>• Mutual funds</td>
<td></td>
<td>• Indirect compensation arrangements</td>
</tr>
<tr>
<td>• Specific providers</td>
<td></td>
<td>• Referral services</td>
</tr>
<tr>
<td>• Publicly-traded securities</td>
<td></td>
<td>• Obstetrical malpractice insurance subsidies</td>
</tr>
<tr>
<td>• Mutual funds</td>
<td></td>
<td>• Professional courtesy</td>
</tr>
<tr>
<td>• Specific providers</td>
<td></td>
<td>• Retention payments in underserved areas</td>
</tr>
<tr>
<td>• Publicly-traded securities</td>
<td></td>
<td>• Community-wide health information systems</td>
</tr>
<tr>
<td>• Mutual funds</td>
<td></td>
<td>• Electronic prescribing items and services</td>
</tr>
<tr>
<td>• Specific providers</td>
<td></td>
<td>• Electronic health records items and services</td>
</tr>
</tbody>
</table>
APPENDIX B

### Anti-Kickback Statute Safe Harbors

- Investment interests
- Space rental
- Equipment rental
- Personal services and management contracts
- Sale of practice
- Referral services
- Warranties
- Discounts
- Employees
- Group purchasing organization
- Waiver of beneficiary coinsurance and deductible amounts
- Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans
- Price reductions offered to health plans
- Practitioner recruitment
- Obstetrical malpractice insurance subsidies
- Investments in group practices
- Cooperative hospital service organizations
- Ambulatory surgical centers
- Referral arrangements for specialty services
- Price reductions offered to eligible managed care organizations
- Price reductions offered by contractors with substantial financial risk to managed care organizations
- Ambulance replenishing
- Health centers
- Electronic prescribing items and services
- Electronic health records items and services
APPENDIX C

CHECKING AN INDIVIDUAL’S EXCLUSION STATUS

I. Determine number of names to be checked against the List of Excluded Individuals/Entities (LEIE)

a. If checking many names, download the LEIE database to your computer. Downloading the database will enable use of spreadsheet or database program search functions. The database can be downloaded at http://oig.hhs.gov/exclusions/exclusions_list.asp.

b. If checking a few names, use the online searchable LEIE database. Five names can be searched at one time. The online database is available at http://exclusions.oig.hhs.gov/.

II. Preparing to Search for an Individual or Entity

a. Make sure to use the correct spelling of the name of the individual or entity being checked against the exclusion database. If the name contains punctuation, the correct punctuation must be included (e.g., the apostrophe should be included for names such as “O’Brien,” “O’Shea,” etc.). Capitalizing letters, however, is not required.

b. It is possible that the OIG has spelled the name of the individual or entity wrong when entering it into the database, so checking multiple variations of the spelling of a name may be appropriate.

c. Specific considerations for searches for individuals:

i. Individuals with hyphenated names should be checked under each of the last names in the hyphenated name (e.g., Jane Smith-Doe should be checked under Jane Smith and Jane Doe).

ii. Make sure to search for former names used by an individual (e.g., maiden name, previous married name, etc.), not just the individual’s current name.

   1. The LEIE database includes only the name known to the OIG at the time the individual was excluded, so failing to check for former names may result in “false negatives.”

d. Specific considerations for searches for entities:

i. Begin your search with the first letters of the entity’s name. For example, a search beginning with “Healthcare” might return a
company called “Healthcare Company ABC,” but it would not return a company called “ABC Healthcare Corporation.”

III. Conducting the Search for an Individual or Entity

   a. Select the appropriate search (single individual, multiple individuals, single entity, or multiple entities).

   b. Make the search as simple as possible. Enter only the first few letters of the last name (for an individual) or the company name (for an entity).

   c. Click in either the Last Name or First Name box (or both) (for an individual) or the Entity Name box (for an entity) and enter part of the name. If searching for multiple individuals or entities, enter the information for each individual or entity into a different row on the form, i.e., only one name should be included per row.

   d. Click the search button.

   e. Click on the column headers to sort the results by a particular column.

IV. Verify the Results

   a. Finding a matching first and last name in the LEIE database is not sufficient to verify that an individual has been excluded. Verification must be done using an individual’s Social Security Number (SSN) or an entity’s Employer Identification Number (EIN). Verification must be done using the online database due to applicable privacy laws.

   b. In the search results list, click on an excluded individual's last name or on the hyperlinked entity name.

   c. Review the data displayed in the verification form.

   d. Click in the text box underneath the data table and enter the SSN or EIN provided to you by the individual or entity, respectively.

   e. Click on the Verify button.

   f. Verification results will be displayed in a message below the form.

      i. If the database does not contain a SSN for an individual or an EIN for an entity, then the number is not available from OIG and the individual’s or entity’s identity cannot be verified using this method. The Exclusions Staff can be contacted to determine if there is any other information available that can assist with verification.
V. Document the Results

a. Print the search results. If there are no matches to the search, the page indicating that there were no matches can be printed. If there are matches, the page indicating whether the identity was verified should be printed.

b. Maintain documentation of the initial name search (or searches) performed and any additional searches conducted in order to verify results of potential name matches.

VI. Additional Information

a. Additional information about exclusion and using the LEIE online and downloadable databases is available on the OIG web site at http://oig.hhs.gov/exclusions/index.asp.

i. An instructional video on using the online database is available at http://oig.hhs.gov/exclusions/online.asp.

ii. An instructional video on using the downloadable database is available at http://oig.hhs.gov/exclusions/download.asp.

b. The OIG’s Exclusions Staff can be contacted at:

HHS, OIG, OI
Attn: Exclusions
P.O. Box 23871
Washington, D.C. 20026
sanctions@oig.hhs.gov
Telephone: (202) 691-2311
Fax: (202) 691-2298

c. The System for Award Management (“SAM”) also contains debarment actions taken by various Federal agencies, including exclusion actions taken by the OIG. Businesses that receive payment from federal health care programs should not employ, contract with, or otherwise do business with individuals or entities that are listed as debarred, suspended, or otherwise excluded from federal programs.

i. The SAM website is available at http://www.sam.gov, and instructions on how to use the SAM website, including FAQs, user guides, and other resources, can be accessed via the “HELP” tab on the SAM website.
ii. Although the SAM website includes information on exclusions, the OIG recommends that providers use the LEIE as the primary source of information about OIG exclusions because the LEIE is maintained by the OIG, is updated monthly, and provides more details about persons excluded by the OIG. In addition, the OIG’s exclusion staff can respond to questions about and verify information contained in the LEIE.25
APPENDIX D

Potential Indirect Compensation Arrangement Analysis

Three step analysis for determining whether an indirect compensation arrangement exists based on the definition of “indirect compensation arrangement” at 42 C.F.R. §411.354(c)(2)

1. Are the referring physician (or immediate family member) (“Physician”) and the entity furnishing designated health services (“DHS”) connected by an unbroken chain of multiple (i.e., more than one) people or entities that have financial relationships between them?
   - If “No,” then there is no indirect compensation arrangement.26
   - If “Yes,” proceed to the next step.

2. Does the Physician receive aggregate compensation from the person or entity in the chain with which the Physician has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS (“varies with referrals”)?
   - Aggregate compensation can vary with referrals even if the individual unit of compensation satisfies the Stark law’s special rules on unit-based compensation.
   - If the direct financial relationship involving the Physician is an ownership or investment interest, use the non-ownership relationship closest to the Physician to determine whether aggregate compensation varies with referrals.
     - If “No,” then there is no indirect compensation arrangement.
     - If “Yes,” proceed to the next step.

3. Does the entity furnishing DHS have actual knowledge of, or is it acting in reckless disregard or deliberate ignorance of, the fact that the Physician receives aggregate compensation that varies with referrals?
   - If “No,” then there is no indirect compensation arrangement.
   - If “Yes,” then there is an indirect compensation arrangement.
ABOUT THE AUTHORS

Linda Baumann is a partner at Arent Fox LLP, where she leads the Health Care Group in Washington, DC and the group's national Compliance/Internal Investigations team. She has extensive experience on a wide range of health care regulatory, litigation and transactional matters, particularly those relating to fraud and abuse, False Claims Act investigations, compliance, and reimbursement. Recognized nationally for her expertise in the Stark Law, the anti-kickback statute and the False Claims Act, Linda helps defend clients who are dealing with federal and/or state government investigations, handling all aspects from initial audit through successful negotiation and settlement. She also helps clients conduct internal investigations, return overpayments, and make formal self-disclosures, when necessary. She often is able to help clients reduce the scope and amount of their liability, e.g., by demonstrating the legality of their practices, narrowing the scope of exposure and/or negotiating favorable settlements.

To help clients reduce the risk of exposure, Linda provides compliance training particularly with regard to physician contracting, conducts due diligence in connection with acquisitions and financing, and helps clients structure transactions to promote business goals while ensuring compliance.

Linda has worked with organizations throughout the industry ranging from Fortune 50 companies to community providers, including hospitals, nursing homes, drug and device manufacturers and distributors, therapy companies, clinical laboratories, DME suppliers, home health agencies, insurers, investors and many others. She has been recognized as a Leading Health Care Lawyer in Chambers USA, Super Lawyers, Legal 500, and The Washingtonian. She is one of the few attorneys nationwide ranked AV Preeminent by Martindale Hubbell. Linda also has served as Chair of the 10,000 member ABA Health Law Section.

Linda is the Editor in Chief of Health Care Fraud and Abuse: Practical Perspectives, a treatise used nationwide and now in its 3rd edition (2013). She frequently speaks before national conferences, and has published numerous articles on health law topics.
ABOUT THE AUTHORS

Sam Cohen is an associate in the Arent Fox Health Care group in Washington, D.C. Sam’s practice focuses on providing advice to clients regarding compliance with health care fraud and abuse laws, with an emphasis on the Stark law and anti-kickback statute. Sam also advises clients on internal and external investigations, particularly investigations related to the False Claims Act, as well as on the HIPAA regulations, reimbursement issues, licensing requirements, and other compliance matters.

As part of his practice, Sam helps health care clients respond to government subpoenas, address related compliance issues, and negotiate associated settlement agreements and corporate integrity agreements, and he also assists clients with drafting, implementing, and evaluating both fraud and abuse and HIPAA compliance programs. Sam has helped clients with all aspects of making voluntary self-disclosures, including the drafting and submission of self-disclosures to the OIG Self-Disclosure Protocol and the CMS Self-Referral Disclosure Protocol. He also conducts due diligence as part of acquisitions to confirm that target companies are complying with all applicable health care regulations.

Sam is the author and co-author of multiple publications, including a chapter on corporate compliance programs in the American Bar Association Health Law Section’s health care fraud and abuse treatise and chapters on the Stark law and HIPAA in a PLI health care litigation handbook. He also is the author of a forthcoming chapter on compliance programs in a new book from the American Health Lawyers Association for attorneys representing hospitals and health systems. Sam has spoken on the Stark law on multiple occasions, including for the American Bar Association, as well as on other topics.

ENDNOTES

1 Certain “all payor” federal and state laws that impose restrictions on contracts that involve private (commercial) payors are outside the scope of this discussion.

2 42 U.S.C. §1395nn; see 42 C.F.R. §§411.351 et seq.

3 Several courts have recently indicated that the Stark law also applies to Medicaid, but there is still some uncertainty in this area of the law. Thus, for a conservative approach, in-house counsel should assume that references to Medicare (in discussions of the Stark law) also include Medicaid, as appropriate. As noted above, in-house counsel should consult with experienced health care counsel for specific legal advice on this issue.

4 The Stark law defines an “immediate family member” or “member of a physician’s immediate family” as a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. 42 C.F.R. §411.351. All subsequent references to “immediate family member” mean an immediate family member as defined by the Stark law.

5 42 C.F.R. §411.353(a).

6 42 C.F.R. §411.353(b).


8 Designed health services are (i) clinical laboratory services, (ii) physical therapy, occupational therapy, and outpatient speech-language pathology services, (iii) radiology and certain other imaging services, (iv) radiation therapy services and supplies, (v) durable medical equipment and supplies, (vi) parenteral and enteral nutrients, equipment, and supplies, (vii) prosthetics, orthotics, and prosthetic devices and supplies, (viii) home health services, (ix) outpatient prescription drugs, and (x) inpatient and outpatient hospital services. 42 C.F.R. §411.351.

9 42 U.S.C. §1320a-7(b).


11 42 U.S.C. §1320a-7(b)(3); 42 C.F.R. § 1001.952.

12 18 U.S.C. §§1347, 1349


15 See 42 U.S.C. §1320a-7(a); 42 C.F.R. § 1003.102.

16 42 U.S.C. §1320a-7(a).

17 42 U.S.C. §1320a-7(a).

18 42 U.S.C. §1320a-7(c)(3)(B).

19 42 U.S.C. §1320a-7(b).


21 66 Fed. Reg. 856, 944-45 (Jan. 4, 2001). While the regulatory preamble mentions all the methodologies described in the text, some of the methodologies are likely to be more credible than others.


23 Id. Note, however, that it is typically the Department of Justice (“DOJ”) that enforces the fraud and abuse laws, and DOJ may have a different perspective on what constitutes (and proves) that an arrangement involves fair market value compensation and/or is commercially reasonable.

24 See http://oig.hhs.gov/exclusions/tips.asp.


26 If there is only one financial relationship between a physician and the entity that furnishes or bills for DHS, the financial relationship typically will be a direct financial relationship.