Chapter 2

Practical and Ethical Concerns When Counseling in the Gray Areas: Structuring Business Arrangements Compliant with Fraud and Abuse Laws[1]

2.1 Introduction

Health care transactional attorneys are often asked to give advice to clients regarding the legality of a proposed business structure, and to assist with drafting the related agreements, where the attorney is not in a position to definitively assess the legality of a proposed structure. In particular, advising and counseling a client with respect to potential risk under the federal Anti-Kickback Statute (AKS)[2] can raise such issues unless the client's proposed arrangement can fit into one of the AKS safe harbors located at 42 C.F.R. § 1001.952, since legality of the arrangement turns on whether there is "intent" to induce referrals.[3]

The primary focus of the chapter is the AKS, given that it is an intent-based statute and potentially applies to virtually all business transactions where reimbursement from governmental health care programs is involved. However, the content of this chapter generally also applies when analyzing other fraud and abuse laws, including, without limitation, the federal physician self-referral law, 42 U.S.C. § 1395nn (Stark Law) and the False Claims Act, 31 U.S.C. §§ 3729 et seq. (FCA).

Frequently, situations arise where the client's proposed conduct falls within a gray area under the fraud and abuse laws. In some cases, no definitive guidance from regulatory authorities may exist with respect to a specific proposed structure, and the best an attorney can do is advise the client regarding factors that could either mitigate or increase the level of risk. Or, such a situation may arise because the attorney has been provided limited factual information. The terms of a proposed structure or agreement as communicated to the attorney may not on their own raise concern under the fraud and abuse laws, but without significant diligence regarding communications between a client and other business partners or referral sources, the attorney may not have the full picture regarding the underlying intent of the parties and goals of the arrangement. And given the time and cost that would be required for such a diligence effort, it would be unrealistic in many cases to expect clients to agree to, or pay for, such an undertaking in the regular course of representation.

When providing prospective compliance advice to a client or assisting to set up a business structure, it is important to consider how best to advise the client regarding activities that could put

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[1] This section was prepared primarily by Amy Joseph, Jordan Kearney, and Charles Oppenheim, of Hooper, Lundy & Bookman, PC. Special thanks to Timothy J. Dacey, Goulston & Storrs PC for his substantial assistance.

[2] 42 U.S.C. § 1320a-7b(b). Similar anti-kickback provisions exist under state law. *See, e.g.,* Cal. Bus. & Prof. Code § 650. The scope of such laws vary, such as with respect to whether the statute applies in the private insurance context or regardless of payer, but often are similar to the federal counterpart.

[3] The statute has been interpreted to cover any arrangement where just one purpose of the remuneration was to obtain money for referral of services or to induce further referrals. *See, e.g., United States v. Greber,* 760 F.2d 68 (3d Cir. 1985), *cert. denied,* 474 U.S. 988 (1985).

it at risk, given that the penalties a client could face for violation of the fraud and abuse laws could be significant,[4] every nuance of a business relationship entered into by a provider could be subject to scrutiny, and this area is one of heightened enforcement.[5]

In addition, it is important to consider the interplay with professional responsibility rules, given how complex the fraud and abuse legal landscape is and how difficult it can be for someone in the attorney's position to have sufficient information (whether factual information from the client or definitive guidance from regulators) to determine whether a client's proposed course of conduct would violate the applicable laws. This chapter provides an overview of the professional responsibility rules that could potentially come into play,[6] as well as addresses practical considerations when providing advice or assistance to a client with respect to a proposed business arrangement.

2.2 Duty to Inquire and Respond to Potentially Problematic Conduct

2.2.1 Assisting Client Crimes or Frauds and Limits of Representation

Professional responsibility rules prohibit attorneys from knowingly assisting a client in a crime or fraud. For example, Model Rule 1.2(d) provides:

> A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law.[7]

In this context, for an attorney to have knowledge he or she must have "actual knowledge of the fact in question."[8] When an attorney has such knowledge, the attorney must "consult with the client about any relevant limitation on the lawyer's conduct."[9] And if the issue cannot be resolved through consultation with the client, Model Rule 1.16(a) provides that the attorney *must* decline representation or, if representation has commenced, withdraw, if the representation would "result in violation of the rules of professional conduct or other law." It is important to note, however, that comments to the rule further provide that the attorney "is not obliged to decline or withdraw simply because the client suggests such a course of conduct; a client may make such a suggestion in the hope that a lawyer will not be constrained by a professional obligation."

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[4] For example, violation of the AKS constitutes a felony punishable by imprisonment as well as a monetary fine. Other consequences may include exclusion from federal health care programs, including Medicare and Medicaid, and the imposition of civil monetary penalties. There is also a risk of AKS violations causing FCA violations, as Section 6402(f)(1) of the Affordable Care Act provides that AKS violations also result in the submission of false claims actionable under the FCA. 42 U.S.C. § 1320a-7b(g).

[5] According to the Health Care Fraud and Abuse Control (HCFAC) Program Report, released by the Department of Health and Human Services (HHS) and the Department of Justice (DOJ) in January of 2017, in Fiscal Year 2016 the federal government recovered more than $3.3 billion in fraudulent health care claims. https://oig.hhs.gov/publications/docs/hcfac/FY2016-hcfac.pdf (last visited May 25, 2017).

[6] This chapter primarily summarizes the ABA Model Rules of Professional Conduct (Model Rules). However, various states may have different or additional rules that apply depending on where the attorney is licensed to practice.

[7] For the sake of comparison, California's Rule of Professional Conduct 3-210 provides that "a member shall not advise the violation of any law, rule, or ruling of a tribunal unless the member believes in good faith that such law, rule, or ruling is invalid." In California, attorney conduct is also governed by California Business & Professions Code Section 6000 et seq.

[8] Model Rule 1.0(f). "A person's knowledge may be inferred from the circumstances." *Id.*

[9] Model Rule 1.4(a)(5). Further, the comments to Model Rule 1.2 provide that if a lawyer "comes to know or *reasonably should know* that a client expects assistance not permitted by the Rules of Professional Conduct or other law . . . , the lawyer must consult with the client regarding the limitations on the lawyer's conduct," indicating that a lawyer may not bury his or her head in the sand. Model Rule 1.2, Comment No. 13 (emphasis added).

Model Rule 1.16(b) also provides that the attorney *may* (but is not required to) withdraw if the client "persists in a course of action involving the lawyer's services that the lawyer reasonably believes criminal or fraudulent" or "the client has used the lawyer's services to perpetrate a crime or fraud." Here, a lawyer has "reasonable belief" when "the lawyer believes the matter in question and that the circumstances are such that the belief is reasonable."[10] Comments to the Model Rule further provide that withdrawal is permissive in such cases, "for a lawyer is not required to be associated with such conduct even if the lawyer does not further it."

Therefore, in situations where an attorney is asked to assist with drafting an agreement that the attorney knows violates fraud and abuse laws, the rules are clear that the attorney must decline to provide such assistance. Such an example could arise if an attorney is asked to draft a medical director agreement between a hospital and a referral source where an attorney knows that the physician will not provide any services in the role as medical director and the agreement is effectively a sham in order to provide remuneration to induce referrals.

However, the trickier scenario is where a client may be engaging in conduct that is potentially criminal or fraudulent, but the attorney does not have the information needed to be sure. For example, situations could arise where the client's proposed course of conduct could violate fraud and abuse laws, but given some ambiguity in the law, an argument exists that could support the client's position. Or, the client could present certain facts that introduce an element of uncertainty that could raise questions under the AKS, but upon inquiry the client has affirmed there is no requisite intent to engage in conduct in violation of the law. In such cases, if the lawyer reasonably believes the conduct will violate fraud and abuse laws but does not know one way or the other, the rules provide some flexibility for an attorney to use his or her best judgment and do not require withdrawal from representation.

Given that the AKS is a criminal, intent-based statute, these types of scenarios are almost certain to arise at some point in a health care transactional attorney's career. Ultimately, the Model Rules provide some comfort that there is flexibility in many (but not all) circumstances to continue working with the client in some manner, if the attorney opts to do so, and advise on how to comply with fraud and abuse laws. Just as different clients have different levels of risk tolerance, the same is true of attorneys, and there is not one best practice to follow in such a situation.

This chapter does not purport to provide detailed advice on compliance with professional responsibility rules. However, as a general rule, if such questions arise in the course of advising on applicability of fraud and abuse laws, those questions should not be treated lightly. When in doubt, an attorney is well-advised to consult with a colleague, the general counsel for the attorney's organization (if applicable), or another attorney that specializes in professional ethics, for advice regarding how to proceed. Just as the potential penalties for a client can be significant, the potential penalties for the attorney can also be significant. In addition to loss of licensure or other disciplinary action by the state bar or civil liability resulting from malpractice litigation, potential consequences could include indictment for aiding and abetting, obstruction of justice, or conspiracy, depending on the circumstances.[11]

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[10] Model Rule 1.0(i).

[11] In addition to an attorney's potential exposure to professional discipline and civil liability, there have been cases in which attorneys were themselves indicted for violation of fraud and abuse laws. *See, e.g.,* https://www.justice.gov/usao-ndtx/pr/executives-surgeons-physicians-and-others-affiliated-forest-park-medical-center-fpmc (last visited May 25, 2017) (DOJ indicted a workers' compensation attorney, among others, alleging that the attorney received approximately $100,000 in bribe and kickback payments in exchange for referring patients); https://archives.fbi.gov/archives/tampa/press-releases/2011/ta030211a.htm (last visited May 25, 2017) (general counsel indicted for conspiracy to commit Medicaid fraud relating to expenditure information for behavioral health care services).

2.2.2 Obligation to Disclose Client Crimes or Frauds

If a client decides to proceed in a course of action constituting a crime or fraud and the attorney withdraws from representation, the attorney's obligations may not end at that point. The attorney should consider whether he or she will take further action outside of withdrawing from the representation, and ensure that any such action is in compliance with the applicable professional responsibility rules. A detailed analysis of the Model Rules and corresponding state rules regarding the obligation to disclose client crimes or frauds is outside the scope of this chapter.[12] However, at a high level, a lawyer may have discretion to disclose information to prevent a client fraud or crime that is reasonably certain to cause substantial financial injury to a third party.[13]

In addition, attorneys who represent organizations must be mindful that their obligations are to the organization itself, not its individual directors, officers, or employees. When an attorney knows that an officer, employee, or other person associated with the organization is violating a law that reasonably might be imputed to the organization and that is likely to result in substantial injury to the organization, the lawyer must proceed as is "reasonably necessary in the best interest of the organization," which will ordinarily include an obligation to report up the chain within the organization.[14] If the highest authority within the organization proceeds so as to clearly violate the law and "the lawyer reasonably believes that the violation is reasonably certain to result in substantial injury to the organization," the lawyer, depending on the circumstances, may reveal information relating to the representation to persons outside the organization to prevent harm to the organization, whether or not the normal rules of confidentiality would allow the disclosure.[15]

Of note, pursuant to the Model Rules, reporting outside the organization is not mandatory and an attorney who makes such a report does so with some risk of violating the duty of confidentiality, as well as the potential risk to the lawyer's own reputation. If, for example, it is determined that it was not reasonable to believe the disclosure was necessary to prevent substantial injury to the organization, the lawyer's breach of confidentiality would not be excused. Also, the exception to the confidentiality rules that allows reporting of a violation of law outside of an organization does not apply "with respect to information relating to a lawyer's representation of an organization to investigate an alleged violation of law, or to defend the organization or an officer, employee or other constituent associated with the organization against a claim arising out of an alleged violation of law."[16]

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[12] This section briefly addresses disclosure under Model Rules 1.6 and 1.13. If the client is subject to federal securities laws, reporting within the organization and permission to disclose outside the organization may also be governed by regulations issued under the Sarbanes Oxley Act. 17 C.F.R. § 205.1 et seq.

[13] Model Rule 1.6(b)(2); *but see* fn. 16. Model Rule 1.6 also addresses other scenarios pursuant to which disclosure is permitted, which are not addressed in this chapter.

[14] Model Rule 1.13(b).

[15] Model Rules 1.6, 1.13(c). However, the applicable state professional responsibility rules in some states are more stringent in such instances, and do not permit disclosure to prevent injury to third parties or to an organizational client. *See, e.g.,* N.Y. R. Prof. Conduct 1.6. 1.13(c); Ca. R. Prof. Conduct 3-600(C); Cal. Bus. & Prof. Code § 6068(e).

[16] Model Rule 1.13(d). On a related note, courts have held that disclosures under the *qui tam* provisions of the FCA are limited by the professional rules that apply to the lawyer. *See U.S. v. Quest Diagnostics*, 734 F.3d 154 (2d Cir. 2013) (recognizing the relator, the former general counsel, may have had limited permission to reveal some confidential information under New York's version of Rule 1.6(b), but holding that his disclosures went far beyond what the rule permitted and upholding disqualification of the relator and dismissal of the case); *U.S. ex rel Holmes v. Northrop Grumman,* 642 Fed.Appx. 373 (5th Cir. 2016) (upholding a decision to disqualify an attorney as a *qui tam* relator, noting that the attorney "is obligated to abide by his ethical obligations as a lawyer—even in FCA cases.").

2.3 Practical Considerations

2.3.1 Advising Clients When the Law Is Ambiguous

In some cases, the analysis with respect to a particular proposed arrangement, and the corresponding advice to the client, is clear. For example, with respect to the medical director agreement addressed above, if the client states that the referral source will not be providing any services and the goal is to strengthen the referral relationship, the analysis is fairly straightforward. However, it is rare that such a scenario, where the client proposes direct remuneration expressly in exchange for patient referrals, will occur—or at least it is rare for a client to propose such a scenario to an attorney.

In other cases, however, there will not be a statute, regulation, or other guidance on point that squarely addresses how to proceed in compliance with fraud and abuse laws, and clients look to counsel to determine what conduct is permissible and how far the envelope can be pushed.

For example, with respect to the Stark Law, the Senate Committee on Finance, Majority Staff released a white paper in 2016 summarizing feedback from stakeholders on the law's ambiguities, unintended consequences, and the need for reform.[17] The white paper states that "Congress intended the Stark Law to provide a bright line test to curb physician self-referral. But despite CMS's efforts to provide clear rules and interpretations to address the strict liability regime, the Stark Law's breadth, complexity, and impenetrability have created a minefield for the health care industry."[18] One of the areas of ambiguity highlighted in the white paper is as follows:

> If a physician has a financial relationship with an entity, any referrals by the physician to that entity are prohibited unless the financial relationship fits within one or more exceptions. But the round table participants characterized the exceptions as illusory because the three key standards in most exceptions—fair market value, "takes into account" volume or value of referrals, and commercially reasonable—are factual, which means parties must prove their arrangement fits into the exception at trial. Moreover, the participants and commenters noted that the three standards are ambiguous, and thus lead to unpredictable outcomes.[19]

By analogy, the so-called "60-day rule" requires providers to report and return an overpayment within 60 days of identifying it.[20] Under the 60-day rule regulations, a provider has identified an overpayment when it "has, or should have through the exercise of reasonable diligence," determined it has an overpayment and calculated the amount.[21] This "reasonable diligence" standard raises many questions in the course of an internal investigation. Reasonable diligence is established "through the timely, good faith investigation of credible information."[22] If a provider becomes

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[17] *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models,* Senate Finance Committee Majority Staff Report (June 30, 2016), *available at* http://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff%20063016.pdf (last visited May 25, 2017).

[18] *Id.* at 2.

[19] *Id.* at 5. As another example under the Stark Law, there is some ambiguity regarding the definition of "entity," although it is a threshold issue to any Stark Law analysis. 42 C.F.R. § 411.351 was amended to clarify the definition of entity (*see* 73 Fed. Reg. 48433, 48751 (Aug. 19, 2008)), but CMS received a number of inquiries seeking further guidance on the definition. Although CMS solicited comments to determine whether further guidance was necessary (*see* 74 Fed. Reg. 61737, 61933 (Nov. 25, 2009)), it ultimately declined to provide additional guidance, stating that "[p]roviders and suppliers may seek further guidance through the advisory opinion process." *See* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Definition_of_Entity.html (last visited May 25, 2017).

[20] 42 U.S.C. § 1320a-7k(d)(1); 42 C.F.R. § 401.305(a)(1).

[21] 42 C.F.R. § 401.305(a)(2).

[22] 81 Fed. Reg. 7654, 7662 (Feb. 12, 2016).

aware of a specific issue and initiates an investigation, it may receive credible information of other potentially problematic issues in the course of that investigation. It can sometimes be difficult to determine at what point the provider can reasonably stop its investigation.

In addition, much of the compliance guidance available from regulators comes in the form of OIG advisory opinions. Advisory opinions can be a helpful resource by providing insight into the likely position that the OIG would take with respect to other similar situations. However, the usefulness of these opinions is somewhat limited, because although they are binding and can be relied on by the requestor of the opinion, they are not binding as to any other parties. Further, the more variation that exists between a proposed arrangement and a scenario described in an OIG advisory opinion, the less assurance there is that regulators would take the same position with respect to the proposed arrangement.

When there is ambiguity, the attorney should advise the client on what is known given current available case law interpretations, enforcement actions, regulatory guidance, and other resources, including prior experience with other matters, so the client is aware of the ambiguity and can decide how to proceed. As addressed above, Model Rule 1.2(d) expressly states that although an attorney may not knowingly assist a client to commit a crime or fraud, an attorney "may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law." The comments further state that Model Rule 1.2(d) "does not preclude the lawyer from giving an honest opinion about the actual consequences that appear likely to result from a client's conduct," and "[t]here is a critical distinction between presenting an analysis of legal aspects of questionable conduct and recommending the means by which a crime or fraud might be committed with impunity."

However, in doing so, the attorney should take care not to paint a rosier picture than warranted or downplay the ambiguities or associated level of risk. There is pressure from some clients for attorneys to be "deal makers" not "deal breakers." Other clients have little patience for an answer beyond a simple "yes" or "no" in response to whether the client can proceed with a proposed structure (and, of those clients, some have little patience if the answer is anything except "yes"). The attorney's advice will likely direct the client's course of conduct; and the client likely will determine whether to enter into a proposed arrangement based on the attorney's advice. If subsequent events prove contrary to the attorney's advice, the client is likely to be displeased. Although some clients are less receptive than others to nuanced advice, if counsel is clear on the legal ambiguity and the limits of counsel's advice on the front end, the client will be better informed and the client's expectations should be easier to manage.

2.3.2 The Difference between Legal Advice and Risk Analysis

A client will often ask about the practical risk in a proposed arrangement, in addition to advice on its legality. Legal advice, as opposed to a practical risk analysis, can be defined as the attorney's assessment of the legal ramifications that could result from a client's course of conduct, and often includes a recommendation from the attorney about how to proceed. In contrast, a practical risk analysis can be defined as an attorney's assessment of the likelihood that a client will suffer legal consequences from some past, present, or proposed conduct given the current enforcement environment.

If the attorney believes that advising on the level of risk of enforcement (aside from the substantive risk of violating the law, e.g., the penalties that would be imposed) is appropriate, the attorney should take care with how such a risk analysis is presented to the client. The attorney should be careful not to indicate to a client that it should proceed in a course of conduct that is probably illegal, simply because the practical risk of enforcement seems low. If communicating that

the proposed course of conduct by the client has not been an area of enforcement activity in the past, the lawyer should also communicate that there is no guarantee there will not be enforcement actions in the future. Priorities of administrations could change, or if enough businesses start engaging in certain conduct, it may garner the attention of regulators and be subject to more scrutiny.[23]

2.4 Key Issues when Structuring a Business Arrangement

2.4.1 Compliance with AKS Safe Harbors

It likely goes without saying that when advising on structuring a business arrangement, the safest course of action is if the client can structure the arrangement to fit within one of the safe harbors to the AKS.[24] However, if the proposed structure does not fit within a safe harbor, generally it is sound advice for the client to find ways to adjust the arrangement to get as close to one of the safe harbors as reasonably possible, in an effort to eliminate or reduce elements viewed as problematic by the OIG, and include elements viewed by the OIG as tending to mitigate the risk of fraud or abuse.

However, even relatively straightforward advice to structure a transaction to fall within a safe harbor, or get as close as reasonably possible, has nuances. For example, one of the elements of the AKS safe harbor for multi-specialty physician-owned ambulatory surgery centers (ASCs)[25] is that each physician investor who is in a position to refer to the ASC perform at least one-third of his or her total Medicare-covered ASC procedures at the ASC in question. This safe harbor is unique because it is the only safe harbor which is conditioned on a certain level of referrals from the physician to the party offering or paying remuneration to the physician (here, the ASC). Many health care attorneys take the position that requiring physician investors to refer to the ASC, and compelling divestment of the physician's ownership if he or she fails to make the threshold number of referrals, is advisable in order to meet the elements of the safe harbor or get as close as possible. However, other health care attorneys take the position that it is risky to require physician investor referrals to the ASC, because if just one element of the safe harbor is not met—whether it be the one-third requirement or some other element—the client is now requiring referrals to the ASC as a condition to remaining in a position to receive remuneration from the ASC (which would normally be the core of a violation of the AKS) without safe harbor protection.

2.4.2 Factors That Could Mitigate or Increase Risk

Often when an attorney is asked to advise on the compliance of a proposed structure or draft the related agreements, the attorney is doing so based on limited information that the client is sharing for purposes of the requested engagement. It is advisable that the attorney raise this issue with the client to explain the limits of the attorney's advice, particularly if this is a new attorney-client relationship and/or the client is not familiar with fraud and abuse laws. Whether this is addressed when defining the scope of representation in the engagement letter, as required in Model Rule

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[23] For example, in the early 2000s, many skilled nursing facilities began increasing the amount of therapy provided to Medicare Part A patients, which resulted in increased Medicare reimbursement. In 2010, enough providers were doing this that OIG reported on the trend. *See* Questionable Billing by Skilled Nursing Facilities, December 2010, OEI 02-09-00202. By 2017, several FCA settlements over $100 million each have resulted from allegations about therapy utilization from the early 2000s to the present. It is important to remember that conduct that is commonplace now may be subject to enforcement many years later, especially given the long statute of limitations under the FCA.

[24] In addition, the structure should fit within an exception to the Stark Law, if applicable. Unlike the AKS safe harbors, which are not mandatory, if the Stark Law applies, the arrangement must meet all elements of one or more Stark Law exceptions. Because there is not the same discretion with respect to the Stark Law, this section focuses on ASC safe harbors.

[25] 42 C.F.R. § 1001.952(r)(3).

1.5(b), or when providing subsequent advice (e.g., in an opinion letter, which should be clear that the attorney is basing the analysis on certain assumed facts as communicated by the client), the attorney should communicate that he or she can advise based only on the information provided to him or her. Given the cost to engage an attorney, it may be reasonable to limit the attorney's involvement in this manner, so long as the client is clear on the limits of the attorney's representation.[26]

2.4.2.1 Practical Suggestions

Even when limited facts are presented by the client, some factors generally support the argument that a proposed structure does not violate AKS. Therefore, to mitigate risk, the attorney might consider the following, as appropriate to the situation:

- Advise that the client engage an independent appraisal company experienced in health care valuation to assess whether the proposed remuneration is fair market value, without taking into account the volume or value of any referrals or business generated for which payment may be made under a federal health care program. If the client does not plan to engage an independent appraiser, whether due to financial constraints, limited timeframe for completing the transaction, or for other reasons, the attorney should consider advising that, at a minimum, the parties document how fair market value was determined.
- Advise that services in exchange for remuneration must be meaningful and commercially reasonable and provide feedback and recommendations as to scope of services customary in similar relationships, as appropriate.
- Advise that the client clearly document the business justifications for the arrangement, including articulation of the fact that the arrangement does not include remuneration intended to induce referrals. Of course, merely documenting such a statement in an agreement or elsewhere does not make it true, but if the client's other actions align with such a statement it could be another helpful factor to evidence compliance.
- Advise that all documentation must accurately reflect the arrangement between the parties, and the more detail that can be provided, the better (e.g., a time log to track hours spent, and duties performed, pursuant to a medical director agreement).
- Advise that the client have ongoing compliance measures in place (if not already addressed by a compliance committee or other oversight mechanism) to ensure that the original lawful intent of the business arrangement is properly implemented, and that the parties fulfill their respective obligations under the arrangement.

In addition, there are multiple factors which may merit further inquiry and advice with respect to AKS compliance. Such factors are too numerous to identify in this chapter, and will vary depending on the circumstances. However, as a general rule of thumb, when analyzing financial relationships, it is useful to examine the amount and nature of any compensation, especially the nexus or link between remuneration paid and referrals received. For example, the presence of one or more of the following factors in a compensation arrangement would tend to make a compensation arrangement more suspect under the AKS, because either the amount of remuneration or the method of remuneration could create an inference that one purpose of the remuneration is to induce referrals: (1) payments to a referral source that are conditioned or contingent on referrals (i.e., either the payments would stop if the referrals were to stop, or the referrals would stop if the payments were to stop); (2) payments to a referral source in excess of fair market value; (3) provision of

[26] *See* Model Rule 1.4(b), which provides that "a lawyer shall explain a matter to the extent reasonably necessary to permit the client to make informed decisions regarding the representation."

valuable items and services to a referral source for free or at less than fair market value; (4) payments to a referral source that correlate with referrals (e.g., the aggregate amount of payments increase/decrease in proportion to the volume or value of referrals); and (5) payments to a referral source for items or services that are not used or needed, or are not needed in the quantity purchased.[27] Conversely, remuneration that is not conditioned or contingent on referrals, that is consistent with fair market value, that does not fluctuate or vary with referrals, and that is for items and services actually needed and used, is less likely to be considered as inducing referrals.

As another example, a few risk factors in the context of a proposed services agreement with a referral source could include vague generalities with respect to the services to be performed, a compensation amount that does not on its face appear to align with the amount and scope of services provided, or a bonus incentive with limited specificity regarding benchmarks to earn such bonus payment or that is paid at the discretion of the person making the payment. Although none of these factors, on their own, indicate a violation of the AKS, they could trigger the need for an attorney to inquire further into the proposed transaction and underlying intent.

2.5 Due Diligence in Connection with a Proposed Transaction

Another area where similar issues arise for health care transactional attorneys is in the context of due diligence related to a proposed transaction, when counsel helps to identify potential fraud and abuse compliance issues with respect to the seller's business. Such diligence on behalf of the buyer or funding/lending source is critical, because identified fraud and abuse compliance issues could inform how to structure the arrangement, as well as drive negotiations of the definitive agreements (e.g., lower purchase price, extended survival period or higher indemnification cap for certain issues, or delay in closing pending resolution). Or, if the compliance issues are significant enough, it could cause the buyer to re-evaluate whether to move forward with the transaction at all. Similarly, such diligence on behalf of the seller is recommended in many cases, so that if there are any potential fraud and abuse compliance issues the seller can identify such issues and proactively address before disclosing to the buyer.

In addition to general inquiries regarding the seller's correspondence with regulators, and pending or threatened investigations, there are a number of due diligence activities which are recommended to assist with identifying potential arrangements that require further review under the fraud and abuse laws, depending on the scope of the representation and the size of the transaction (in some cases, in depth due diligence is cost-prohibitive for a client). Some examples include:

- Reviewing a sampling of various contracts with health care practitioners and other referral sources, and all templates for such agreements, if review of all contracts is cost-prohibitive;
- Reviewing any appraisals or other materials documenting that compensation provided pursuant to such contracts is fair market value (and noting which agreements do not have such documentary support);
- Engaging a consultant to perform a billing audit for a sampling of claims;
- Reviewing descriptions and related documents for joint ventures or other relationships with referral sources;
- Reviewing policies and procedures with respect to fraud and abuse compliance, such as

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[27] *Cf.* Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4866 (Jan. 31, 2005) ("The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the volume or value of any past or future referrals or other business generated between the parties.").

physician contracting policies and policies addressing free or discounted items or services to Medicare or Medicaid beneficiaries;

- Reviewing the corporate compliance program and compliance committee minutes, to the extent applicable, to determine the compliance culture and level of oversight;[28] and
- Reviewing strategic plans, progress reports, or other materials prepared by individuals responsible for business development. Such documents may provide insight into intent that is different than what would be in a document that has been subject to review and revision (and possibly sanitized) by seller's counsel.

In the course of due diligence, if the client or the attorney identifies a perceived issue with an existing arrangement which could increase risk under fraud and abuse laws, the attorney may decide that it is appropriate to assist the client with revising the agreements and restructuring the relationship moving forward. In such a case, conduct to avoid would include, among other things, backdating documents or altering original operative documents, as opposed to amending the documents. The focus should be on addressing the issue prospectively, as well as advising the client whether further internal investigation, which could potentially lead to overpayments and self-reporting, is recommended.[29]

2.6 Documenting Client Consultations

It is advisable that an attorney document his or her conversations with the client, as well as with any third party, when an attorney's advice is provided in an area of uncertainty (which can occur fairly regularly when advising on fraud and abuse laws). The attorney should also consider documenting the representations made by the client, any limitations on the advice given by the attorney to the client, and communications where the lawyer has specifically noted to the client that a proposed arrangement, while not illegal per se, involves some level of risk.

The extent and nature of the documentation will vary depending on the preference and practice style of each attorney. Regardless, when communicating with the client (e.g., via email) or documenting and filing a summary of the communication (e.g., after a phone call consultation), it is important to keep a few things in mind. First, given the frequency of changes of management, ownership and/or control in the health care industry, including changes in leadership, as well as mergers, acquisitions, affiliations, and re-organizations, it is best to assume that the individual who is seeking counsel today on behalf of a health care client may be replaced by another person whose history with the client may be shorter or nonexistent, and whose tolerance for risk may be substantially different. To the extent that a client is opting to engage in conduct that involves some risk, it is advisable to document the fact that the client was informed of the legal risks when making a determination about how to proceed. Second, as discussed in Chapter 6,[30] it is best to keep in mind that whatever an attorney writes about or receives from a client may become evidence, even if it is presumably protected by the attorney-client privilege when initially written.

2.7 Know Your Limits

One of the basic premises of legal representation is that the attorney must provide competent representation, meaning, among other things, the attorney has the "legal knowledge . . . reasonably

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[28] A useful resource for such review is the DOJ Criminal Division Fraud Section's guidance, Evaluating Corporate Compliance Programs, *available at* https://www.justice.gov/criminal-fraud/page/file/937501/download (last visited May 25, 2017).

[29] See Chapter 5 regarding an attorney's role in conducting compliance audits and internal investigations.

[30] See Chapter 6 regarding privilege protection.

necessary for the representation."[31] This concept goes hand in hand with the prior topics addressed in this chapter, because a high level of knowledge is needed to effectively counsel a client on fraud and abuse compliance, particularly given the complexity of this area of law, and the number of gray areas involved.

Advising on compliance with fraud and abuse laws when structuring a business arrangement is particularly difficult given that the legal landscape is continually changing. For example, in 2016 alone, the OIG issued 13 advisory opinions (in addition to modifying or terminating other advisory opinions), and there have also been multiple special fraud alerts and advisory bulletins in recent years. And while there has been increased enforcement in certain areas, more flexibility is also being indicated in other circumstances, such as new AKS safe harbors effective in January 2017 and other recent rulemaking and guidance with respect to fraud and abuse laws.[32]

Furthermore, in addition to advising on the federal side, most states have counterparts to the federal fraud and abuse and physician self-referral laws which must also be considered when advising a client to provide a complete picture.[33] The complexity multiplies when advising clients that operate on a national scale, such as clients launching nationwide health care mobile apps or engaging in telemedicine across state lines.

In short, because health care fraud and abuse laws are complex and changing, it can be a dangerous practice area for a generalist, or a health care attorney that generally focuses on other types of legal issues. While it is important for all health care attorneys to have at least a working knowledge of fraud and abuse laws in order to spot issues as they arise, it is equally important to understand and recognize the limits of one's knowledge, and either consult with a colleague that specializes in the area or refer out as needed.

2.8 AHLA Resources

AHLA's Fraud and Abuse Practice Group provides multiple additional resources to assist a health care transactional attorney in navigating the dangerous waters of fraud and abuse, including a fifty state survey of applicable fraud and abuse statutes, regulations, and other pertinent authority, as well as AKS, health care real estate lease, and Stark Law toolkits. In addition, AHLA's Business Law and Governance Practice Group provides a due diligence checklist toolkit, which contains sample due diligence checklists for a variety of transactions, and each checklist includes certain due diligence requests that facilitate diligence with respect to fraud and abuse compliance.

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[31] Model Rule 1.1.

[32] *See, e.g.,* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368 (Dec. 7, 2016); Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70886, 71373–78 (Nov. 16, 2015) (revising Stark Law regulations, including new exceptions for recruitment of non-physician practitioners and timeshare arrangements); Medicare Program; Final Waivers in Connection with the Shared Savings Program Final Rule (issued jointly by OIG and CMS on Oct. 29, 2015); Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model (issued jointly by OIG and CMS on Nov. 16, 2015).

[33] *See, e.g.,* Cal. Bus. & Prof. Code §§ 650, 650.01, and 650.02, Cal. Health & Saf. Code § 445, Cal. Lab. Code §§ 139.3, 139.31, and 3215, Cal. Ins. Code Section 1871 et seq.