# Interactions between Medical Technology Companies and Health Care Professionals: Updates to the AdvaMed Code of Ethics and Federal Anti-kickback Statute Implications


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The Advanced Medical Technology Association (AdvaMed), a trade association of medical technology companies, has announced an update to its *Code of Ethics on Interactions with U.S. Health Care Professionals* (Code), effective January 01, 2020.[1] The Code, first introduced in 1993 and updated in 2003 and 2009, consists of ethical guidelines for interactions between U.S. health care professionals, including individual practitioner and provider entities (HCPs), and companies that develop, produce, manufacture, and market medical technologies used in the delivery of health care ("medical technologies"). Recognizing that HCPs' "first and highest duty is to act in the best interests of their patients," the Code encourages medical technology companies ("companies") to promote an organizational culture that supports ethical practices and prevents and detects inappropriate conduct.[2]

AdvaMed strongly encourages companies to adopt the Code as part of an overall culture of compliance and to "avoid interactions [with HCPs] designed to circumvent the Code."[3] While the Code is not legally binding and does not replace laws or regulations, it is intended to establish a foundation for compliance with health care fraud and abuse laws and regulations, such as the federal anti-kickback statute (AKS). Indeed, the Code is largely based on the fundamental principles outlined in the AKS and its implementing regulations and guidance from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), which is applicable to all health care providers who

bill federal health care programs, such as Medicare and Medicaid.[4]

As further described below, while arrangements between companies and HCPs are often legitimate, some arrangements between companies and HCPs have, in many instances, been utilized to disguise payments meant to induce or reward HCPs for future or past referrals and have been the basis of government enforcement actions under the AKS and the federal False Claims Act.[5] Accordingly, it is exceedingly important that both companies and HCPs maintain robust compliance programs to ensure that financial relationships between companies and HCPs comply with the AKS and other fraud and abuse laws and related guidance.

In this article, we first outline major changes to the Code, which include revisions related to the following: consulting arrangements with HCPs; the provision of technical support in the clinical setting; communications related to the safe and effective use of medical technology; jointly conducted education and marketing programs; company-conducted programs and meetings with HCPs; educational and research grants, charitable donations, and commercial sponsorships; the provision of health economics and reimbursement information; and demonstration, evaluation, and consigned products. Next, we summarize the requirements of the AKS and a safe harbor applicable to many arrangements between companies and HCPs, as well as relevant OIG guidance. Lastly, we outline certain high-level compliance best practices regarding arrangements between companies and HCPs to mitigate the risk of government enforcement actions.

## AdvaMed Code of Ethics Revisions

### Consulting Arrangements with Health Care Professionals

The Code recognizes that companies legitimately rely on HCPs' expertise in many significant ways.[6] For example, companies rely on HCPs for training, research, and the development of new, safe, and effective technologies and products.[7] HCPs, however, also play a critical role in deciding or strongly influencing which medical technologies are used in the treatment of patients, and studies have shown that "the impulse to reciprocate for even small gifts has a powerful influence on behavior."[8] Because companies have seized on that impulse, the government views consulting arrangements between companies and HCPs as susceptible to fraud and abuse. A study conducted by the OIG found that, during the years 2002 through 2006, four manufacturers, which controlled almost 75 percent of the hip and knee replacement market, paid physician consultants over $800 million through approximately 6,500 consulting arrangements. While many payments, according to the report, were legitimate, some were not.[9] According to the government, often these types of arrangements represent companies' attempts to induce or reward referrals from HCPs, a tactic that can result in the use of overpriced or substandard equipment, ultimately driving up the costs of health care.[10]

For these reasons, since at least 2003, the Code has included consulting guidelines that promote transparency and discourage unduly influencing HCPs' decisionmaking with lucrative contracts and extravagant trips. Those guidelines have been largely unchanged for the past 16 years. The updated Code expands important existing concepts related to legitimate need, separation between the selection process and sales personnel, and criteria to establish fair market value for consulting arrangements.

#### Legitimate Need

Like the current Code, the updated Code emphasizes that a company should only enter a consulting arrangement with an HCP if it has identified a legitimate need

for the HCP's *bona fide* services in advance of entering into the arrangement. The updated Code, however, revises the definition of "legitimate need." Rather than simply stating that these arrangements require "a proper business objective," the updated Code states that a legitimate need exists when the company requires the services of the HCP to achieve a specific objective, and provides multiple examples, such as the need to train other HCPs on the technical components of safely and effectively using a product, the need for clinical expertise related to product research and development, or the need for a physician's "expert judgment" on clinical issues related to a product.[11] While the current Code prohibits engaging an HCP for the purpose of generating business, the updated Code expands this concept, specifically excluding arrangements designed to generate business or to reward referrals from the contracted HCP (or anyone affiliated with such HCP).

#### Consultant Selection and Separation of Company Sales Personnel

The updated Code underscores the importance of consultant selection, which should be based on the HCP's qualifications, after being "duly vetted" by the company in accordance with the company's legitimate need. Examples of qualifications include the HCP's specialty, years of experience, location, practice setting, clinical research experience, podium presence, and speaking and publication experience.[12] Like the existing Code, the updated Code references experience with, usage of, or familiarity with a specific medical technology and emphasizes that neither selection of nor compensation to a consultant should be a "reward for past usage" or an "unlawful inducement for future purchases."[13] The updated Code further advises that companies should "implement safeguards so that consultants are not selected based in whole or in part on sales considerations."[14]

In furtherance of assuring that companies select consultants for reasons other than sales, the updated Code places greater emphasis on a prohibition by sales personnel of controlling or unduly influencing the decision to engage a particular HCP. According to the updated Code, companies should "consider implementing" controls that will promote compliance with these requirements.[15] A new FAQ explicitly addresses the underlying issue, explaining that "[t]he Code requires this separation to avoid the perception that a Company has entered a contract with a Health Care Professional for purchasing, using, or recommending the Company's Medical Technology or other sales considerations."[16] Thus, to avoid the appearance of consultant selection based on sales volumes or as an inducement for future purchases, which would invite scrutiny regarding the legitimacy of the consultant arrangement altogether, companies should develop protocols that do not allow sales personnel to control or directly influence consultant selection.

#### Establishing Fair Market Value

As an element of assuring that compensation is fair market value, the updated Code advises companies to confirm that the services performed by the HCP are consistent with the agreement. The updated Code further explains how a company can establish fair market value, specifically referencing third-party vendors or other experts who can assist in developing an approach. Like the current Code, the updated Code reiterates that the method for establishing fair market value should include objective criteria, but the updated Code provides several examples of such criteria: the HCP's specialty, years and type of experience, geographic location, practice setting, the type of services performed, etc. (note that these also are factors to consider in selection of an appropriate consultant).[17]

This section of the Code references payment of actual expenses incurred by a consultant necessary to carry out the consulting arrangement, but payments for travel, modest meals, and lodging are referred to in a new Section VI and a revised Section VII of the Code.

## Company Representative Providing Technical Support in the Clinical Setting

In keeping with AdvaMed's overall recognition of the advancement of medical technologies and their increasing importance to the delivery of quality, life-saving patient care, and perhaps in recognition of current practice, the updated Code includes a new section that explicitly addresses company representatives providing technical support in the clinical setting.

The updated Code acknowledges that it is often helpful to have company representatives in the clinical setting to support the safe and effective use of medical technology in real time and to assist clinical teams in the operating room with the technical aspects and unique settings of any devices or accessories. When developing protocol for company representatives in such clinical settings, HCPs should be aware of the following recommendations outlined in the Code:

- Company representatives should be present in the clinical setting only at the request of and under the supervision of a qualified HCP.
- Company representatives should be transparent that they are acting on behalf of the company in a technical support capacity.
- Company representatives should not interfere with an HCP's independent clinical decisionmaking.
- Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
- A company's technical support should not eliminate an overhead or other expense that the HCP otherwise would incur while providing patient care.[18]

HCPs should consider any operational issues that may arise with having company representatives onsite and should outline all expectations clearly in a written agreement. HCPs also should be cognizant of risk management concerns with allowing company representatives into clinical settings and may consider requiring increased professional liability or cyber liability insurance coverage or detailed indemnity provisions, as appropriate, to address these risks. Furthermore, the company's role in assisting HCPs and/or patients may mean the company can access and use the HCP's protected health information (PHI) as a "health care provider" under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA),[19] which may alter the way the HCP interacts with the company with respect to PHI. In this regard, a business associate agreement would not be required; however, a written agreement should clearly identify the terms of the arrangement and the relationship and should include a requirement that the company comply with HIPAA and indemnify the HCP for any breach of PHI.

## Communicating for the Safe and Effective Use of Medical Technology

In recognition of the increasing complexity and utility of medical technology, and the importance of such medical technology to the delivery of high-quality patient care, the Code includes a new section specific to communications among company representatives and HCPs related to the safe and effective use of medical technology. This provision recognizes that U.S. law, including FDA regulations, allow for "off-label" uses of medical technology, meaning uses not approved or cleared but in the best interest of the patient.[20] Because access to accurate information is "critical to a HCP's

ability to exercise his or her medical judgment in the best interests of patients," information regarding off-label uses should be (1) identified as such, (2) provided by the company's authorized personnel, and (3) truthful and nonmisleading.[21]

Examples of appropriate communication of information related to both on- and off-label uses include peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines; presentations at educational and medical meetings regarding clinical trial results or research and development data for investigational use; and discussions between consultants and HCPs regarding, for example, unmet patient needs and product research and development.[22]

## Jointly Conducted Education and Marketing Programs

This new section of the Code explains that companies and HCPs may partner to jointly conduct programs to educate patients and other HCPs on medical conditions and available testing methods and treatment options, including the availability of the company's medical technology and the HCP's ability to diagnose and treat certain medical conditions. One example is an event in which the company shares information about its medical technology to an audience of HCPs or patients, and a physician speaks about the medical conditions the medical technology is intended to treat, procedures that use the medical technology, and the physician's ability to perform those procedures.

For these programs, "[a] Company and a HCP should serve as *bona fide* partners, and contributions and costs should be shared fairly and equitably between the parties."[23] This means that the company and HCP share costs, expenses, and responsibility for planning such an event. To the extent the company seeks simply to promote and educate about its medical technology, it could consider engaging the HCP as a consultant, subject to the guidance outlined in the section regarding engaging with consultants.

Additional guidelines include:

- The Company must have a legitimate need to engage in the joint activity.
- Companies should establish controls to ensure that a decision to engage in the arrangement is not for the purpose of an unlawful inducement (*i.e.*, in violation of the federal AKS).
- Content should be balanced, promoting both the company and its medical technologies and the HCP and the range of services offered to diagnose and treat the applicable medical conditions.
- The arrangement should be documented in a written agreement that sets forth the arrangement's purpose, and the roles, responsibilities, and costs of each party.[24]

## Company-Conducted Programs and Meetings with Health Care Professionals

Section III consolidates two former sections of the current Code: Section III, Company-Conducted Product Training and Education, and Section V, Sales, Promotional, and Other Business Meetings.

### Company-Conducted Training and Education

Given the increased complexity of many medical technologies,[25] company training is, in many instances, essential. The provisions on company-conducted product training and education under the current and updated Codes generally recognize that companies have a responsibility to provide training on the safe and effective use of their products. Revisions in the updated Code are primarily focused on an acknowledgement of the expanded role and increased complexity of medical technology within the context of patient care. The Code emphasizes that medical technology may involve "complex equipment, devices, and/or sophisticated software platforms that require technical

instruction," and further that procedures in which a company's medical technologies are used may be "complex and require skilled clinical instruction."[26] The updated Code expands the scope of training and education from simply "how Medical Technologies benefit certain patient populations," to disease states and treatment options, patient selection criteria, clinical treatment standards and outcomes, and care pathways, emphasizing that "[a]ll of this information contributes to the safe and effective use of Medical Technology."[27]

The updated Code also adds a requirement that HCPs must have a legitimate need to attend company-conducted training and education programs.[28]

#### Company Business Meetings

Certainly, there are legitimate needs for business meetings that involve HCPs, but historically these arrangements have been susceptible to abuse by companies looking to influence decisionmakers. Some examples of these arrangements include "meetings" at resort locations that last only a few hours per day, with the remainder of the day available for meals and recreational activities, all at the expense of the company.[29] In view of this history, but in further recognition that medical technologies have become increasingly important in the delivery of health care, this section has been significantly revised, primarily to bolster guidelines related to need, but also to expand examples of the types of business meetings that might include HCPs.

The company and the HCP must have a "legitimate need" for business meetings, and each HCP in attendance should have an "objective, legitimate need" to attend.[30] Some examples of such need include a discussion of company service offerings, the impact of products on the delivery of health care, and health economics information.[31] Other needs may be to show HCPs aspects of the company's manufacturing process, including how the company makes its technology. Examples of the types of meetings now include plant or facility tours, equipment demonstrations, and "meetings to explore product development or clinical testing needs."[32] Likewise, meeting venue has been expanded to include the HCP's place of business, another centralized location, or the company's own facility when such is "a more appropriate setting."[33] The updated Code underscores that the "setting for a Company conducted program or meeting must be conducive to the discussion of relevant information."[34]

In a separate section, a new provision of the Code "strongly encourage[s]" Companies to develop policies on providing meals that are modest and on an occasional basis.[35]

## Educational and Research Grants, Charitable Donations, and Commercial Sponsorships

AdvaMed combined the current sections of the Code related to sponsorship of educational conferences, research and educational grants, and charitable donations into one comprehensive section related to the provision of grants, donations, and commercial sponsorship. This new Section IV contains additional guidance and clarification on the provision of such sponsorship and provides helpful checklists to assist in structuring compliant arrangements. The new section also outlines as key concepts that companies and other organizations play an important role in educating HCPs and patients, providing charitable donations, and supporting life-changing research, but that companies "should establish processes and guidelines so that decisions to support Third-Party Programs are made objectively and not used as unlawful inducements to HCPs."[36] Updates include:

- Examples for which third-party recipients may use educational grants;[37]
- New guidelines for the level of commercial sponsorships, which "should

reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the company, such as advertising, signage, display/exhibit space, or other promotional opportunities;"[38]

- A reiteration that sales personnel should not control or influence grant or support decisions, including who should receive grants or support and the amount of such support;
- A checklist of controls to assist companies in reviewing requests to support third-party programs;[39]
- An expansion and clarification of the requirements for supporting independent research programs through grants;[40]
- A new section regarding donations for indigent care, which requires that such donations "serve exclusively to benefit patients and are permitted under applicable laws," and suggests that companies make donations contingent upon the recipient hospital's agreement that no third parties will be billed for the donated product.[41]

## Provision of Health Economics and Reimbursement Information

Revisions to this section are generally nonsubstantive, with the exception that the updated Code affirmatively recognizes that coverage, reimbursement, and health economics information is critical to accessing medical technology. The updated Code also clarifies that companies may provide HCPs with assistance in obtaining patient coverage decisions from payors by providing information—*not training*—on payor policies, and training on procedures for obtaining prior authorization. Lastly, the updated Code reminds companies that they should not provide free services that eliminate an overhead or other expense that an HCP otherwise would have incurred as part of its business operations (such as pre-authorization services of physician's professional fees) and removed the conditional language "if doing so would amount to an unlawful inducement."[42]

## Demonstration, Evaluation, and Consigned Products

The updated Code elaborates on the factors that will determine the length of time necessary for an "appropriate" evaluation of multiple use products, such as frequency of anticipated use, duration of any required training, the number of HCPs who need to evaluate the product, the amount of time needed to evaluate different product features, and others.[43] The updated Code also adds a requirement that the length of time should be "consistent with any applicable transparency reporting requirements," such as the U.S. Physician Payments Sunshine Act.[44] Written terms should specify the length of the evaluation period and address products that have not been returned within the evaluation period.

This section also includes a new subsection that specifically addresses consigned products, which are defined as medical technologies (a) that a company provides to an HCP for use in and storage at the HCP's patient care setting, and (b) to which the company retains title until the product is used. The updated Code specifies that HCPs should ensure that a written agreement outlines consignment arrangements and specifically addresses, among other things: the number of products subject to the agreement; any requirements to segregate consigned products from other products; and storage space rental terms, if applicable. Additionally, companies should implement appropriate controls related to consigned products, including a periodic inventory of consigned devices, a reconciliation of discrepancies, and processes for the return or removal of expired products.

We frequently see consignment agreements as part of an overarching product purchase agreement. Often, the HCP executing the agreement is not aware of

the consignment component and has not considered whether consignment is necessary or feasible, nor has it reviewed the agreement to confirm the presence of protective provisions, such as inventory management, onsite access, and return of products. To comply with the AKS safe harbor, HCPs should enter into written agreements with companies for the purchase of *any* products, including those that are sold on consignment. Such agreements should incorporate the terms outlined in the updated Code.

## The Federal Anti-kickback Statute and Applicable OIG Guidance

While compliance with the Code is not compulsory, it is intended to assure compliant and transparent arrangements between HCPs and companies and incorporates many of the principles underlying the federal AKS, as well as other related federal fraud and abuse laws, such as the federal Civil Monetary Penalties Law[45] and the False Claims Act.[46] HCPs and companies should understand the application and impact of the requirements under these federal laws and how the AdvaMed Code, in many respects, reflects and promotes compliance in arrangements historically viewed by government regulators to be prone to fraud and abuse and therefore susceptible to intense government scrutiny. Below, we outline the requirements of the AKS and related OIG guidance with regard to relationships between HCPs and companies. OIG guidance, though not binding, is helpful in terms of providing valuable insight into how the government views certain arrangements between companies and HCPs, as well as the factors that government regulators will consider in analyzing particular arrangement under the AKS.

### The Federal Anti-kickback Statute

The AKS prohibits any individual from knowingly and willfully soliciting, receiving, offering, or paying, directly or indirectly, any remuneration to induce or reward the referral, order, lease, or recommendation of an item or service payable by a federal health care program (including Medicare and Medicaid).[47] The AKS is intent-based, which means remuneration for referrals is subject to liability only if the requisite intent to induce or provide referrals is present. Certain federal circuit courts, however, have held that a payment or other form of remuneration to an HCP violates the AKS if one purpose (as opposed to a primary or sole purpose) is to induce referrals.[48] Additionally, recent Affordable Care Act revisions reiterate that a person need not have actual knowledge of or specific intent to commit a violation of the AKS.[49]

### Personal Services Safe Harbor

The AKS provides a number of "safe harbors" that protect arrangements that, in the government's view, are structured in a manner that mitigate the risk of fraud or abuse. An arrangement, however, must meet each requirement of an applicable safe harbor to receive protection. Arrangements that do not fit within a safe harbor are not *per se* violative but instead are analyzed based on their particular facts and circumstances.

There are a multitude of safe harbors potentially applicable to the various types of arrangements between companies and HCPs, but the safe harbor most relevant to many of the arrangements described above is the Personal Services and Management Contracts safe harbor (the "Personal Services Safe Harbor"). The Personal Services Safe Harbor protects compensation for services rendered if the following requirements are met:

(1) the arrangement must be set forth in a signed, written agreement for a term not less than one year that specifies all of the services to be provided;
(2) the aggregate services must not exceed those that are reasonably necessary to accomplish the commercially

reasonable business purposes of the arrangement;
(3) if services will be provided on a periodic or part-time basis, the agreement must specify exactly the schedule of the services and compensation for such intervals;
(4) the aggregate compensation must be set in advance, consistent with fair market value in an arm's-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties payable under federal health care programs; and
(5) the services must not involve the counselling or promotion of a business arrangement or other activity that otherwise violates any state or federal law.[50]

The AKS safe harbor regulations do not define the term "set in advance." The OIG, however, has interpreted the "set in advance" requirement to mean that the total aggregate compensation to be paid over the term of the contract must be determined at the outset of the arrangement. This requirement can present a challenge to obtaining safe harbor protection for many arrangements. The OIG has specifically clarified that compensation arrangements based on an hourly rate or where the hours of service can vary and arrangements based on units of service (sometimes referred to as "per use" or "per click" compensation) will not qualify for safe harbor protection and explicitly declined to protect such arrangements under the Personal Services Safe Harbor, even though the amount to be paid per unit of service is set in advance. In the OIG's view, these compensation arrangements may be used in an abusive manner.[51] In those types of arrangements, the contract rarely specifies the aggregate compensation at the outset because the amount of services (such as the hours of service) are generally not known in advance.

In addition, the Personal Services Safe Harbor requires that the arrangement be commercially reasonable, meaning that the arrangement has a legitimate business purpose and would make commercial sense even if there were no potential business referrals generated between the parties to the arrangement. Consistent with OIG guidance, this commercial reasonableness requirement is a common thread throughout the Code, which cautions companies that arrangements with HCPs must have a "legitimate need."

#### OIG Compliance Guidance

To promote compliance with the AKS and related laws applicable to federal health care programs, the OIG issued Compliance Program Guidance for Pharmaceutical Manufacturers ("Manufacturer Compliance Guidance"), which identifies potential risk areas for the drug industry and recommends various measures to guard against violating federal fraud and abuse laws, including the AKS.[52] While the OIG has not produced similar compliance guidance for medical device manufacturers, the OIG specifically states that the Manufacturer Compliance Guidance is applicable to "manufacturers of other products" that are reimbursable by federal health care programs, "such as medical devices and infant nutritional products."[53]

The OIG also has issued Compliance Program Guidance for Hospitals (Hospital Compliance Guidance)[54] and Compliance Program Guidance for Individual and Small Group Physician Practices,[55] which similarly outline compliance recommendations to assist those providers in identifying significant risk areas and evaluating and refining ongoing compliance efforts. All of these compliance guidance documents specifically identify financial relationships between manufacturers and HCPs (either physicians or entities) that are referral sources as a key area of risk that potentially implicates the AKS. Accordingly, the OIG advises manufacturers and hospitals

to: (i) identify any financial relationship that implicates the AKS, such as manufacturers and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly, and (ii) determine whether one purpose of the remuneration is to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program. Moreover, the OIG emphasizes that a lawful purpose will not legitimize a payment that also has an unlawful purpose.

Many of the arrangements between manufacturers and HCPs addressed in the Code are referenced in the Manufacturer Compliance Guidance as arrangements particularly susceptible to fraud and abuse, including consulting and advisory payments, payments to HCPs for time spent listening to sales representatives market products, "business courtesies," and educational and research activities.[56] The OIG specifically suggests that manufacturers and hospitals should consider the following when evaluating a proposed arrangement:

- Does the arrangement have the potential to interfere with, or skew, clinical decision-making?
- Is the information provided to decision-makers and prescribers complete, accurate, and not misleading?
- Does the arrangement have the potential to increase costs to federal health care programs or beneficiaries?
- Does the arrangement have the potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement raise patient safety or quality of care concerns?[57]

Perhaps more notably, the OIG's "Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse" (the "roadmap") cautions physicians that some manufacturers have aimed to buy physician loyalty through illegal "sham" arrangements, such as consulting agreements.[58] The roadmap encourages physicians to evaluate the propriety of the proposed arrangement and the connection between the offered compensation from a manufacturer and the services to be provided by the physician by asking him or herself the following: whether the manufacturer really needs the physician's particular expertise or input; whether the amount of money the manufacturer is offering seems fair, appropriate, and commercially reasonable; and whether it is possible the manufacturer is paying for the physician's loyalty to prescribe its drugs or use its devices.[59]

The roadmap further explains that drug and device manufacturers often sponsor continuing medical education events, but stresses the importance of distinguishing between CME sessions that are educational in nature and sessions that are promotional.[60] Similar to the above, the roadmap encourages physicians to evaluate offers to serve as faculty for industry-sponsored CME by asking the same questions above, as well as whether the sponsor prepares a slide deck and speaker notes, or whether the physician is free to set the content of the lecture.[61]

Much like the Code, each of these OIG guidance documents aims to promote compliance with the AKS and other laws applicable to federal health care programs and to assist companies and HCPs in developing and implementing internal controls, policies, and procedures that promote adherence to such laws.

## Compliance Best Practices

Arrangements between companies and HCPs are subject to the AKS and related government guidance and have historically (and continue to be) the subject of intense scrutiny by the federal government. The updated Code provides helpful clarifications and additional detail about how best to structure arrangements between companies and HCPs to maintain compliance with the AKS. Ultimately, the key is that arrangements between companies and HCPs must

be commercially reasonable and subject to fair market value payments that directly relate to the services provided and are not tied to the value or volume of patient referrals or other business generated between the parties. As stated above, the government will scrutinize each arrangement on a case-by-case basis and in the context of all other arrangements between the company and HCP, but adhering to the compliance best practices outlined below may decrease the risk of government enforcement.

**Safe Harbor Compliance**

Ideally, all arrangements between companies and HCPs would be structured to squarely fit into an AKS safe harbor, to the extent one is available. With regard to company-HCP arrangements where one party is providing services to the other (such as when an HCP is acting as a consultant), the Personal Services Safe Harbor is applicable. As discussed above, the Personal Services Safe Harbor requires, among other things, aggregate compensation set in advance, and it is not always possible to meet this requirement and ensure that the compensation will remain fair market value if the amount of service provided cannot be accurately predicted. If meeting all of the requirements of the relevant AKS safe harbor is not possible, the arrangement should track the requirements as closely as possible and, in any case, the compensation between the parties should never be based on the value or volume of federal health care business (or any business) referred to the company. Companies and HCPs should have policies and procedures in place to ensure legal review of all arrangements that do not squarely meet safe harbor requirements.

**Fair Market Value**

While compliance with the AKS requires that compensation between referral sources reflect fair market value, companies and HCPs must ensure that the process for determining the compensation for a proposed arrangement is reasonable, consistent, and objective, and adequately documented. The valuation of any particular arrangement is a fact-intensive inquiry that must take into account factors such as the nature of the transaction, comparable compensation for similarly situated parties (preferably between parties for which no referral relationship exists), and other applicable factors, including those discussed in the updated Code. Engaging an independent third-party valuator to render an opinion with regard to the range of fair market value compensation for a proposed arrangement and setting the compensation consistent with that opinion will mitigate regulatory risk that an arrangement will be viewed as prohibited remuneration under the AKS, absent an illicit intent to induce or reward referrals.

**Legitimate Purpose/Commercial Reasonableness**

As discussed above, the government also expects transactions between health care providers to be commercially reasonable, meaning that the arrangement has a legitimate business purpose and would make commercial sense even if there were no potential business referrals generated. This requirement is prevalent throughout the updated Code. Fundamental to the determination of whether an agreement is commercially reasonable is evaluating whether the arrangement is consistent with fair market value, and any transaction inconsistent with fair market value is, by its very nature, commercially unreasonable. A transaction, however, also may be viewed as commercially unreasonable even if it is consistent with fair market value if it lacks a legitimate business purpose. The updated Code and the OIG compliance guidance provide valuable insight on key factors that parties should consider when evaluating the commercial reasonableness, or legitimate purpose, of an arrangement. The fundamental and most important question to ask is, "Would this arrangement make sense

if there were no referrals between the parties?" Parties should clearly document the legitimate business purpose of the arrangement in a written agreement.

### Compliance Program

Most importantly, companies and HCPs alike should implement and maintain robust compliance programs that are effective at preventing, deterring, and detecting misconduct. In the context of company-HCP relationships, companies and HCPs should maintain policies and procedures that address regulatory requirements, such as the AKS, and outline appropriate (and inappropriate) interactions with other health care industry stakeholders. Likewise, companies and HCPs must ensure that compliance information is communicated throughout the organization and that employees and other staff are educated and trained on the complex regulatory environment, compliance risks, and their own responsibility for compliance within the context of the larger organization.

## Conclusion

In a climate where technology, the availability and use of data, and opportunities to greatly enhance and improve the delivery of health care proliferate, the ability for HCPs and medical technology companies to explore collaborative and educational relationships is essential. Given the significant interactions between companies and HCPs in relation to the development, acquisition, and use of medical technologies and increased government scrutiny of these relationships, maintaining open but transparent and ethical relationships also is critically important. Prior to January 2020, HCPs and companies who regularly contract with one another each should review the updated Code and assess whether current relationships could benefit from a refresher of the Code's ethical principles and specific guidelines. Similarly, companies and HCPs should assess whether any revisions to existing internal policies, procedures, and contracts are in order and should assure affected personnel are appropriately and timely trained.[62]

## Endnotes

1. Revised and Restated AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals, AdvaMed Medical Technology Association, available at *www.advamed.org/sites/default/files/resource/advamed_u.s._code_of_ethics_final_-_eff._jan_1_2020.pdf* (hereinafter referred to as the "Code"). The prior version of the Code, which is in effect until December 31, 2019, may be found at the following link: *www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf* ("hereinafter referred to as the "Prior Code").
2. Code at 2. For clarity, all quotes cited in this alert reference the updated Code, unless otherwise noted.
3. *Id.* at 3.
4. Many state law restrictions also would be applicable to the arrangements between companies and HCPs. For example, many states also have their own anti-kickback statutes, and fee-splitting prohibitions, which are often broader than their federal counterparts and are, in many instances, applicable to all payors (including commercial and self-pay patients). In addition, many states have consumer protection and similar commercial laws that are not limited to the health care context, which may also be applicable to company-HCP arrangements.
5. 31 U.S.C. §§ 3729-3733.
6. Code at 8.
7. *Id.*
8. *Examining the Relationship Between the Medical Device Industry and Physicians*, Testimony of Gregory E. Meske, Assistant Inspector General for Legal Affairs, OIG, DHHS at 1 (Feb. 27, 2008), *available at* oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf [hereinafter, *"Meske Testimony"*].
9. *Id. a*t p. 2.
10. *See e.g. Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America*, U.S. DEP'T OF JUSTICE (Mar. 1, 2016), *www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals* (describing an Olympus settlement related in part to illegal payments provided to doctors and hospitals for device consulting arrangements); *see also Meske Testimony* at 4 (summarizing several settlements involving impermissible consulting arrangements involving medical device suppliers and the criminal conviction of a physician).
11. Code at 8.

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# Hospital May Face Damages for Failing to Provide Interpreter Services for Deaf Patients

## Patients Granted Leave to Amend Prospective Harm Claim, Asserted Adequate Claim for Intentional Discrimination under Federal Laws

A hospital in Illinois may be liable for damages to an engaged deaf couple who were not provided adequate sign language interpreter services during their treatment and stay at the facility after specifically requesting the service, a federal district court in Illinois ruled, holding that their allegations of discrimination under the Rehabilitation Act and the Patient Protection and Affordable Care Act were sufficient to survive dismissal. The court determined that the injunction plea had not been sufficiently pleaded but allowed the couple to replead.[1]

### Background

An engaged couple from Concord, Illinois, both sought medical treatment on several occasions at Memorial Medical Center. Both fiancés are deaf and communicate through American Sign Language with a limited ability to understand written English. Neither can read lips. The couple had informed the staff at the hospital that they required an interpreter, but on over five occasions the hospital failed to provide adequate interpreter services during the procedures and while hospitalized. The couple asserted claims that their rights, individually, had been violated under the Americans with Disabilities Act,[2] the Rehabilitation Act,[3] and the Patient Protection and Affordable Care Act.[4] They sought declarative and injunctive relief to enjoin future violations in addition to compensatory relief.

### Prospective Injunctive Relief

The court determined that the claim for injunctive relief failed because the couple did not allege a "real and