ADVAMED CODE OF ETHICS REVISIONS EFFECTIVE JANUARY 2020: IMPLICATIONS FOR HEALTH CARE PROVIDER INTERACTIONS WITH VENDORS

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U.S. Health Care and FDA Alert

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, 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 (“HCPs”) and companies that develop, produce, manufacture, and market medical technology used in the delivery of health care (“Medical Technology”). Recognizing that HCPs' “first and highest duty is to act in the best interests of their patients,” the Code encourages Medical Technology companies (each a “Company” and collectively, “Companies”) to promote an organizational culture that supports ethical practices and prevents and detects inappropriate conduct. [2]

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”). 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]

Given the significant interactions between Companies and HCPs in relation to the development, acquisition, and use of Medical Technologies, maintaining open but transparent and ethical relationships is critically important. Particularly in light of increased governmental scrutiny of vendor-provider relationships, HCPs who regularly contract with Companies should review the updated Code and assess whether current vendor relationships could benefit from a refresher of the Code's ethical principles and specific guidelines and whether any revisions to existing vendor policies, procedures, and contracts are in order. [4] Likewise, Companies should examine their existing arrangements with HCPs, update policies and procedures, and train affected personnel prior to January of 2020 to assure compliance with the updated Code. Major changes to the Code are outlined below.

CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

The Code recognizes that Companies legitimately rely on HCPs' expertise in many significant ways. [5] For example, Companies rely on HCPs for training, research, and the development of new, safe, and effective technologies and products. [6] However, HCPs also play a critical role in deciding or strongly influencing which Medical Technologies will be 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.” [7] Because Companies have seized on that impulse, consulting arrangements between Companies and HCPs are one area at risk of fraud and abuse. A study conducted by the Office of Inspector General of the Department of Health and Human Services found that,

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during the years 2002 through 2006, four manufacturers, which controlled almost 75% of the hip and knee replacement market, paid physician consultants over $800 million over approximately 6,500 consulting arrangements. While many payments, according to the report, were legitimate, some were not. [8] According to the government, often these types of arrangements represent Companies' attempts to induce or reward referrals from HCPs, a tactic that often results in the use of overpriced or substandard equipment and ultimately drives up the costs of health care. [9]

For these reasons, since at least 2003, the Code has included consulting guidelines that promote transparency and discourage unduly influencing HCPs' decision-making with lucrative contracts and extravagant trips, but 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 a 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. [10] While the current Code prohibits engaging a 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. [11] 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.” [12] The updated Code, however, also advises that Companies should “implement safeguards so that consultants are not selected based in whole or in part on sales considerations.” [13]

Related to the goal of selecting consultants for reasons other than sales, greater emphasis is placed in the updated Code 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. [14] 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.” [15]

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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. (also factors to consider in selection of an appropriate consultant). [16]

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

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 a HCP's independent clinical decision-making.
- 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. [17]

HCPs should consider any operational issues that may arise with having Company representatives on-site 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. Further, the Company's role in assisting HCPs and/or patients may mean the Company can

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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"), [18] 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, the terms of the arrangement and the relationship should be clearly identified in a written agreement, including 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 Food and Drug Administration ("FDA) regulations, allow for "off-label" uses of Medical Technology, meaning uses not approved or cleared but in the best interest of the patient. [19] 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 non-misleading. [20]

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. [21]

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." [22] 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:

- There must be a legitimate need for the Company to engage in the joint activity.

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- 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. [23]

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, [24] 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.” [25] 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.” [26]

The updated Code also adds a requirement that HCPs must have a legitimate need to attend Company-conducted training and education programs. [27]

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 decision-makers. 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. [28] Within this framework, Medical Technologies have become increasingly important in the delivery of health care. It is no surprise, then, that 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. [29] 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. [30] 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.” [31]

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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." [32] The updated Code underscores that the "setting for a Company conducted program or meeting must be conducive to the discussion of relevant information." [33]

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. [34]

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." [35]

Updates include:

- examples for which third-party recipients may use educational grants; [36]
- 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;" [37]
- 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; [38]
- an expansion and clarification of the requirements for supporting independent research programs through grants; [39] and
- 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. [40]

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

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provide free services that eliminate an overhead or other expense that a 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.” [41]

DEMONSTRATION, EVALUATION, AND CONSIGNED PRODUCTS

The Code is largely unchanged regarding demonstration and evaluation arrangements, though in its requirement that Companies provide appropriate documentation, it specifies that such documentation should allow HCPs to meet their “reimbursement reporting obligations,” no doubt referencing, for example, the reporting requirements of the AKS's Discount Safe Harbor. [42] The updated Code also 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 consignment arrangements are outlined in a written agreement that 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.

CONCLUSION

Recognizing the evolution of Medical Technology and the importance of Company-HCP engagement to the overall delivery of health care, the code emphasizes legitimate need, objective criteria, transparency, and independent decision-making. The Code seeks to establish guardrails that will foster compliant Company and HCP engagement in both the health care and business settings. As stated by AdvaMed's Chair-Elect, Kevin Lobo, Chairperson of Stryker, "These updates continue to focus the industry on positive, necessary collaborations with physicians and other HCPs to bring the most effective and innovative care to patients around the world. By helping ensure companies continue to focus on ethical business practices, the refreshed Code reinforced the industry's commitment to delivering expert care and building products that make a difference for health care professionals and patients." [45]

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The updated Code provides helpful clarifications and additional detail about how best to structure arrangements between Companies and HCPs. Companies and HCPs should carefully review the Code and assess whether any operational changes or contractual arrangements are required prior to the Code's implementation in 2020.

K&L Gates' health care practice can assist HCPs in addressing and updating vendor policies, procedures, and contracts in light of the recent changes to the Code. We regularly advise clients on vendor interactions, conflicts of interest, and other compliance matters and facilitate stakeholder engagement with Congress and the administration through our public policy and law practice.

NOTES:

[1] Revised and Restated AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals, Advanced Med. Tech. Ass'n, https://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 current version of the Code, which is in effect until December 31, 2019, may be found at the following link: https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf.
[2] Code at 2. For clarity, all quotes cited in this alert reference the updated Code, unless otherwise noted.
[3] *Id.* at 3
[4] Provisions of the Code that have not changed from the current version include Educational & Patient Benefit Items; Clinical Studies and Research Arrangements (though now in narrative form rather than only in the "Frequently Asked Questions"); Prohibition on Gifts; Prohibition on Entertainment & Recreation; Travel & Lodging; and Venue. While we have not included these areas of the Code in this summary, HCPs should ensure that any arrangements with Companies are compliant with these guidelines as well.
[5] Code at 8
[6] *Id.*
[7] *Examining the Relationship Between the Medical Device Industry and Physicians*, Testimony of Gregory E. Meske, Assistant Inspector General for Legal Affairs, OIG, DHHS, February 27, 2008 ("*Meske Testimony*"), https://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.
[8] *Id.* at 2
[9] *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 JUST. (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*, p. 4 (summarizing several settlements involving impermissible consulting arrangements, including Zimmer, DePuy Orthopaedics, Biomet, Smith & Nephew, Medtronic, Advance Neuromodulation Systems, and the criminal conviction of a physician).
[10] Code at 8.
[11] *Id.*
[12] *Id.* at 9
[13] *Id.*
[14] *Id.*

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[15] *Id.*
[16] *Id.*
[17] *Id.* at 37.
[18] 45 C.F.R. § 160.10
[19] Code at 29.
[20] *Id.*
[21] *Id.*
[22] *Id.* at 22
[23] *Id.*
[24] In fact, the updated Code's definition of "Medical Technology" acknowledges this increasing complexity. Both the current and updated Code reference specific examples in the definition, including implantables, surgical devices, and noninvasive reagents, instrumentation, and/or software. The updated Code also includes, however, a reference to digital technology and software platforms that aid in the monitoring, diagnosing, and treating of patients and a general definition not present in the Prior Code, which references "medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities." Code at 6.
[25] *Id.* at 12
[26] *Id.*
[27] *Id.* at 13
[28] *Meske Testimony*, p. 5 (referencing a settlement with multiple hip and knee devise manufacturers).
[29] Code at 14.
[30] *Id.* at 13-14.
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.* at 26.
[35] *Id.* at 15.
[36] *Id.* at 16.
[37] *Id.* at 17
[38] *Id.* at 16
[39] *Id.* at 20
[40] *Id.* at 21
[41] *See* Prior Code at 10; Code at 33.
[42] Code at 34.
[43] *Id.*
[44] *Id.*
[45] Press Release, Advanced Med. Tech. Ass'n, AdvaMed Approves Updated Code of Ethics (Jan. 9, 2019), https://www.advamed.org/newsroom/press-releases/advamed-approves-updated-code-ethics.

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