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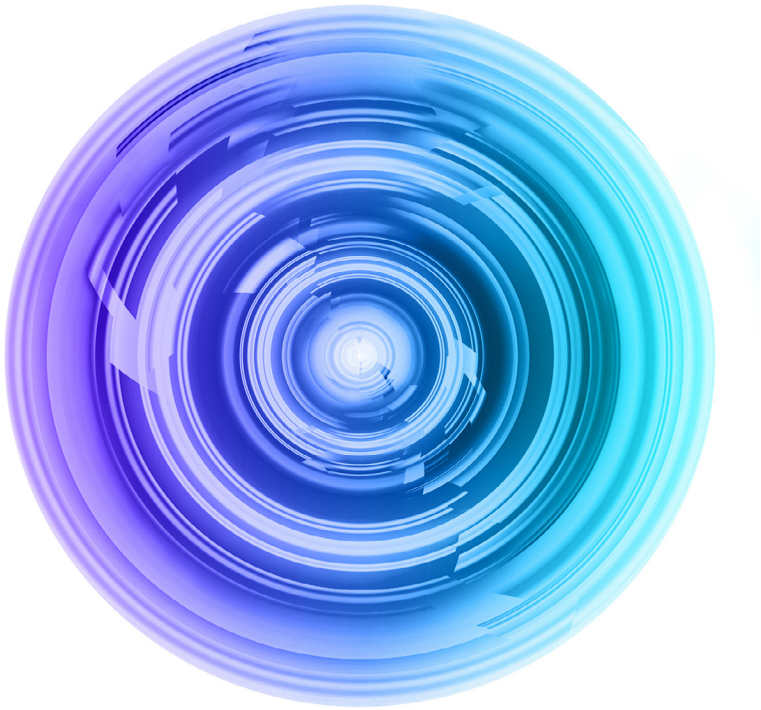

Keep up on MedTech industry compliance

A summary of the June 2022 update of the AdvaMed Code

Overview

On March 24, 2022, the Advanced Medical and Technology Association (AdvaMed) announced[1] that it updated its *Code of Ethics on Interactions with Health Care Professionals (HCPs) in the United States*[2] (updated "AdvaMed Code," "AdvaMed '22," or the "Code"). The AdvaMed Code is a voluntary code of ethics applicable to Medical Technology (MedTech) interactions with US HCPs. The updated AdvaMed Code took effect on June 1, 2022.

The versions of the AdvaMed Code are as follows:

- Effective June 1, 2022
- Effective January 1, 2020
- Effective July 1, 2009
- Effective January 1, 2004
- Original code[3] effective 1993

These compliance guidance updates for MedTech companies follow the earlier industry updates from the Pharmaceutical Research and Manufacturers of America (PhRMA) announcing an update to its *Code on Interactions with HCPs* (PhRMA Code) (January 2022).[4]

AdvaMed '22 provided **six new FAQs** to clarify critical concepts:

- Anti-kickback statute safe harbor
- Applicability of updated AdvaMed Code to value-based arrangements with HCPs
- Alcohol at company events
- Appropriateness of restaurants for company venues
- Refreshments at virtual meetings
- Provision of coverage, reimbursement, or health economics information to HCPs during the negotiation of a value-based arrangement

Code Highlights

Code Certifications

AdvaMed '22 language: "A company that adopts the Code is **strongly encouraged to submit to AdvaMed a certification** stating that the company has adopted the Code and has implemented an effective compliance program."[5]

What has changed: Previously, the Code strongly encouraged companies to submit to AdvaMed an annual certification. The updated AdvaMed Code removes the need to certify annually.[6]

What this means: This is a positive change that allows companies to better manage resources by not strongly suggesting **annual certifications**. Certifying companies may consider implementing monitoring controls around the compliance program to help ensure that the company has implemented an effective compliance program. The monitoring program should include a timely awareness of industry code updates. Whenever there are updates to the AdvaMed Code or other industry alerts applicable to the MedTech industry, the company's monitoring plan should reflect those updates.

Value-Based Care

The updated AdvaMed Code now includes a definition for value-based care[7] and provides further insight to the purpose, training/education efforts, company business meetings, and provision of health economic and reimbursement information.

AdvaMed '22 language:
Value-Based Care: "A health care delivery model in which contributors to care are paid based on individual patient health outcomes, population health outcomes, increasing access to healthcare for underserved populations, managing costs, and/or improving efficiency."[8]

Purpose: Value-based care arrangements "are designed to increase shared accountability among stakeholders for quality of, access to, and/or total cost of care."[9]

Training/Education: When these value-based arrangements include product training and education, MedTech companies are not restricted to medical device education and training. Instead, companies are permitted to provide the needed training for services, software, and equipment designed to facilitate/measure given value-based outcomes.[10]

Company Business Meetings: Value-based solutions, services, and arrangements are now included in the examples provided for legitimate business meetings between MedTech companies and HCPs.[11]

Provision of Health Economics and Reimbursement Information: The advancement of value-based care arrangements and providing accurate and objective information about the use of MedTech technologies is permissible under the updated AdvaMed Code.[12]

What has changed: Previously, the AdvaMed Code made no mention of value-based care or the complexities faced by industry when dealing with these arrangements with HCPs. In addition to addressing value-based arrangements throughout, there are two new FAQs on value-based care to provide additional insight.

FAQ #4 Q: "How does the Code apply to interactions with HCPs relating to arrangements that advance value or outcomes-based care?

A: The Code applies to interactions with HCPs relating to arrangements to advance value-based care the same as it applies to any other interaction with HCPs. The safe harbors and related OIG guidance are designed to facilitate innovative approaches to value-based care and to encourage a broad range of participation and business structures. Accordingly, even if no individual safe harbor may be fully applicable, a specific value-based care arrangement may nevertheless be permissible under the anti-kickback statute based on the particular facts and circumstances."[13]

FAQ #34 Q: "May a company provide coverage, reimbursement, and health economics information to an HCP for the purpose of developing or negotiating a value- or outcomes-based contract between the company and the HCP?

A: Yes, subject to the conditions described in this section, a company may provide accurate and objective information relating to the economically efficient use of its MedTechs, including in the context of value- and outcomes-based contracting. A company may not, however, interfere with a HCP's independent clinical decision-making or provide such information as an unlawful inducement."[14]

What this means: The safe harbors and related Office of Inspector General (OIG) guidance are designed to facilitate innovative approaches to value-based care and to encourage a broad range of participation and business structures for companies to consider. Since the addition of value-based care to the Code is new and these activities may be evolving for companies, it may be beneficial to reevaluate current company policies and business activities as it relates to value-based solutions, services, or arrangements.

Engaging an HCP to provide consulting services:
AdvaMed '22 language:[15] Companies should apply the following principles to all consulting arrangements with HCPs:

Legitimate Need. "A company should enter a consulting arrangement with a Health Care Professional only if it has identified a legitimate need for the Health Care Professional's services in advance.

Consultant Selection. A company should select only duly vetted HCPs to serve as consultants, based on the Health Care Professional's qualifications to meet the identified need. Some examples of these qualifications include the Health Care Professional's specialty, years of experience, location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific MedTech, among other qualifications. A company may not select or compensate consultants as a reward for past usage or as an unlawful inducement for future purchases. A company should implement safeguards so that consultants are not selected based in whole or in part on sales considerations.

Number of Consultants. A company should engage only as many consultants as are necessary to fulfill the company's requirements for the bona fide services.

Fair Market Value Compensation. A company should compensate a consultant consistent with the fair market value in an arm's-length transaction of the services provided. A company should not base compensation on the volume or value of the consultant's past, present, or anticipated business. A company should confirm the services performed by the HCP in accordance with the agreement.

Expenses. A company may pay for documented, reasonable, and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, lodging, and modest meals.

Documentation. A company should maintain appropriate documentation which may include documentation regarding the process for determining legitimate need, fair market value compensation, and other relevant factors.

Written Agreement. A company should enter into written agreements that describe all consulting services to be provided and the compensation to be paid in exchange for the services. When a company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.

Sales Involvement. Sales personnel cannot control or unduly influence the decision to engage a particular HCP as a consultant. A company's sales personnel may provide input about the qualifications of a proposed consultant. A Company should consider implementing appropriate controls to promote compliance with this section."[16]

What has changed: The overarching framework for engaging HCPs in consulting arrangements remained unchanged; however, the update added an additional requirement for "appropriate documentation."[17] This new addition increased the list of principles from seven to eight requirements. Additionally, there is one new FAQ to provide additional insight.

FAQ #3 Q: "What if a proposed interaction with an HCP does not fit into an existing safe harbor to the anti-kickback statute?

A: Not having a safe harbor available (or not meeting all conditions of a safe harbor) for a particular interaction or arrangement does not necessarily mean the interaction would be a violation of the anti-kickback statute. The interaction or arrangement should instead be analyzed for compliance with the anti-kickback statute based on the specific facts and circumstances, including the intentions of both the Company representative and the Health Care Professional behind the interaction or arrangement."[18]

What this means: Effective compliance programs should be designed around appropriate documentation. Certifying companies should review and confirm whether their processes around legitimate need and fair market value compensation are documented. Other process-based factors could be assessed from a risk-based perspective with the company prioritizing the documentation needs for higher risk processes.

Meeting and event considerations (travel, lodging, venue, meals, and refreshments):

AdvaMed '22 language:
Virtual: "An interaction that involves attendees participating in a virtual environment that is generally enabled by digital technology rather than meeting in a physical location."[19]

Legitimate Need: "There must be objective, legitimate reasons that support the need for out-of-town travel. **As an alternative to in-person programs, companies may wish to consider whether the legitimate need could be met via program conducted virtually."**[20]

What has changed: The glossary for the updated AdvaMed Code now includes the term "virtual," and references to the permissibility of virtual settings for meetings, events, and trainings have been included throughout the Code. Additionally, the legitimate need determination for travel, lodging, and venue consideration now includes a suggestion to evaluate virtual settings as an alternative to travel expenses. The previous version of the AdvaMed Code also included examples of legitimate reasons to support the need for out-of-town travel that have been **removed** from the updated AdvaMed Code. These removed examples of legitimate need include:

- Need to deliver training and education concerning MedTechs
- Inability to effectively deliver the content of the program through means other than an in-person meeting
- Need to demonstrate equipment

Additionally, there are three new FAQs to provide additional insight for meeting and event considerations.

FAQ #9 Q: "May companies provide alcohol at company-conducted programs and meetings?

A: Decisions to provide modest refreshments, including alcohol, must comply with the requirements of Section VII of the Code. In furthering the Code's commitment to responsible business practices, companies also may consider adopting controls around the provision of alcohol at company-conducted programs and meetings. For example, considering government guidance, companies may adopt per-person drink limits, per-drink spend limits, limitations on the types of alcohol permitted (e.g., beer and wine only), or disallow alcohol at certain events (such as the types of company-conducted training and education programs. . . Companies may wish to review AdvaMed's periodic benchmarking surveys on best practices around providing modest meals and refreshments, among other topics."[21]

FAQ #10 Q: "When is it appropriate to hold a company-conducted meeting in a restaurant?

A: Companies should consider the factors outlined in the Code when evaluating and selecting a venue."[22]

FAQ #29 Q: "May companies provide meals or refreshments for company-conducted meetings that are held virtually?

A: Yes. Modest meals or refreshments may be provided in accordance with . . . the Code. To properly consider and manage the provision of meals to HCPs during company-conducted meetings that are held virtually, companies may create a process to control ordering and delivery, track attendance to ensure that only appropriate participants in the meeting receive the meals/refreshments, and/or prohibit home delivery."[23]

What this means: Given the vast changes COVID-19 prompted in the life sciences industry, it was expected that the AdvaMed Code would be updated to provide guidance and clarity regarding interactions when dealing with physicians or customers in virtual settings. Compliance professionals already understand the necessity for having processes in place and documentation for the **legitimate need** for consultant arrangements, business meetings, and training and education events, but companies may want to consider updating their processes and controls to properly account for virtual interactions with physicians or customers. If meetings and events are held virtually, companies may consider the following:

- Create a process to control ordering and delivery,
- Track attendance to confirm that only appropriate participants in the meeting receive the meals/refreshments, and
- Prohibit home delivery of meals/refreshments.

What are MedTech companies doing with these changes?

With the vast differences in the types of organizations and solutions that comprise the MedTech industry, companies require flexibility to design compliance programs that appropriately scale to identified risks. Since the updated Code went into effect, Deloitte has observed companies utilizing the updated Code to further mature, modify, and monitor their compliance controls. Below are some proactive measures that companies may consider when deciding on the response to the updated Code:

- Adopt policies and procedures that reflect the company's processes in value-based care arrangements
- Update policies and procedures to reflect virtual capabilities for training and education and company business meetings
- Evaluate and document whether meetings that require HCP travel and expense could be conducted virtually
- Review and update documentation practices for engagements with HCPs
- Audit and monitor to confirm that stakeholders document HCP interactions per company policy
- Assess company's approach to alcohol given industry scrutiny and train stakeholders on any new changes to company policy

The Code also acknowledges that MedTech companies are in a unique position to drive innovation through data-driven solutions.[24] MedTech companies have the ability to leverage health care data and technology to provide solutions, both clinical and business, to improve health care and help trigger innovative and cost-effective care. "Data-driven devices can also work independently or as part of a larger ecosystem to enable data collection, aggregation, and analysis."[25] The purposes behind enabling these data-driven devices vary across tools and companies, but the benefits include the following: [26]

- Enabling new insights and improving analytics
- Supporting health and wellness
- Improving patient interventions and outcomes
- Enhancing the quality/efficiency of health care delivery
- Empowering data collection, aggregation, and analysis

As a final consideration, MedTech organizations can consider engaging experienced professionals with demonstrated methodologies to help design, execute, manage, and report on compliance activities, including compliance program gap assessments, to further mitigate the emerging risks that surround interactions with HCPs.

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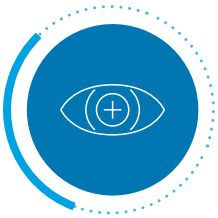

Endnotes

1. AdvaMed, "AdvaMed Approves Updated Code of Ethics" MedTech POV Blog, March 24, 2022.
2. AdvaMed, "Code of Ethics on Interactions with Health Care Professionals (HCPs) in the U.S." effective June 1, 2022.
3. Health Industry Manufacturers Association ("HIMA") Code
4. PhRMA, "Code on Interactions with Health Care Professionals," effective January 1, 2022.
5. AdvaMed '22 at 6.
6. *Ibid.* at 6; see also AdvaMed '20 at 5.
7. Value-based care may also be referred to as the following:
   - Results based care
   - Outcomes based care
   - Performance based payment arrangements
8. AdvaMed '22 at 8.
9. AdvaMed '22 at 8.
10. *Ibid.* at 13.
11. *Ibid.* at 14.
12. *Ibid.* at 31; *See also* FAQ 34.
13. *Ibid.* at 8.
14. *Ibid.* at 31.
15. AdvaMed '22 added the language around the Documentation requirements.
16. *Ibid.*
17. *Ibid.* at 10.
18. *Ibid.* at 5.
19. *Ibid.* at 7.
20. *Ibid.* at 24 (Section VI).
21. *Ibid.* at 12.
22. *Ibid.* at 14.
23. *Ibid.* at 27.
24. *Ibid.* at 3 (Providing new language in the updated AdvaMed code explaining the purpose that data-driven solutions play in the MedTech industry.)
25. *Ibid.* at 3.
26. *Ibid.* at 3.