

# Analyzing the Revised AdvaMed Code: Suggested Evaluation Checklist

## REVIEW INTERNAL POLICY DEFINITIONS TO ALIGN WITH REVISED ADVAMED CODE

- Does your current policy apply to the same “Health Care Professionals” (HCPs) as the Revised AdvaMed Code?** (See *AdvaMed Code*, § I)
- How do your policies address other definitions in the Revised AdvaMed Code** (i.e., Educational Grant, Commercial Sponsorship, Satellite Symposia, Third-Party Conference and Third-Party Conference Organizer)?
- Have you compared your policies’ applicability to the scope and applicability principles laid out in the Code?** (See *Revised AdvaMed Code*, § I)

*\*\*Hospitals and other health care organizations should consider the Revised AdvaMed Code’s definition of “HCP” and language on applicability to understand to which HCPs and industry interactions the Code applies.*

**HCP:** any person or entity (a) authorized or licensed in the U.S. to provide health care services or items to patients or (b) who is involved in the decision to purchase, prescribe, order or recommend a medical technology in the United States. This term includes individual clinicians..., provider entities..., and administrative personnel at provider entities.... This term does not include HCPs who are bona fide employees of a Company.... See *Revised AdvaMed Code*, § I.

## ASSESS CONSULTANT SELECTION PROCESSES

- Do your consulting practices include a periodic needs assessment?**
- Have you adopted a consistent HCP consultant selection process?**
- Do your payment processes align with terms of written consulting contracts?**

The Revised AdvaMed Code reminds companies and HCPs about the need to assess and address **conflicts of interest**. Medical technology companies, hospitals and other health care organizations should consider whether your conflict of interest policies remain up-to-date. See *Revised AdvaMed Code*, § II.

## COMPARE POLICIES ON EDUCATIONAL GRANTS AND COMMERCIAL SPONSORSHIP

- Have you compared your policies’ treatment of educational grants and other types of support for third-party educational conferences?**
- What processes are in place to evaluate requests to support third-party independent educational programs, research programs or charitable programs?**

*\*\*The revised section on Educational Grants maintains the Code’s longstanding limits on direct financial support to HCPs to attend third-party programs, consistent with other industry associations’ standards around the world.*

The Revised AdvaMed Code **distinguishes between Educational Grants and Commercial Sponsorship**. Educational Grants are considered funds or in-kind support to assist a third party in reducing the costs of providing educational content. Commercial Sponsorship, on the other hand, reflects a fee paid by a manufacturer (buyer) to a third-party organizer (seller) to purchase advertising or marketing space. See *Revised AdvaMed Code*, § IV.

## REVIEW TREATMENT OF SATELLITE SYMPOSIA

- Does your company engage in Satellite Symposia** (i.e., Company-organized and funded programs appended to a Third-Party Program agenda but that the Third-Party Organizer does not control)?
- What controls do your policies place on travel, lodging or registration expenses for HCPs attending a Satellite Symposium?**

The Revised AdvaMed Code includes **new Q&A on Satellite Symposia**, establishing controls for HCP attendees’ travel and lodging. Broadly, the purpose of this guidance is to avoid an end-run around the Code’s language limiting direct support for HCPs to attend non-company, third-party organized events. See *Revised AdvaMed Code*, § IV.

**SEE REVERSE FOR ADDITIONAL INFORMATION**

## ANALYZE BUSINESS COURTESIES POLICIES AND REVIEW LIMITS ON HCP MEALS AND HCP TRAVEL AND LODGING

- Do you have controls and/or a policy for the provision of meals and refreshments to HCPs?
- Under what circumstances do you currently cover an HCP's travel and lodging expenses to attend a meeting or program?
- What limits or guardrails do you maintain for location and setting of company meetings?
- What process did you follow to identify, document and analyze these meetings?

*\*\*Keep in mind state and local laws that may limit meals, travel and lodging for HCPs licensed in those jurisdictions. See Revised AdvaMed Code, §§ VI-VII.*

[A 2018 kickback settlement between a medical technology company and the Department of Justice](#) regarding the provision of meals to HCPs shows importance of internal controls. The provision of meals and refreshments to HCPs is also a topic highlighted by the high-volume of meal disclosures under the Sunshine Act.

## ANALYZE JOINTLY CONDUCTED EDUCATIONAL OR MARKETING PROGRAMS

- Do you partner with HCPs to deliver educational or marketing content?
- What controls do you have in place?
- How have you evaluated and allocated responsibilities, contributions, and costs?

*\*\*Hospitals and other health care organizations should be aware of industry guidance on jointly conducted programs, including information on meeting companies' internal policies on delivering off-label information and information about health economics, among other limits.*

New Section V of the AdvaMed Code incorporates **guardrails for companies seeking to engage in jointly conducted educational and marketing programs**. As medical technology companies and providers continue to partner on alternative care delivery models, collaboration to deliver important content to patients and other HCPs may become more prevalent. See Revised AdvaMed Code, § V.

## CALIBRATE POLICIES ON TECHNICAL SUPPORT IN THE CLINICAL SETTING

- Do you have a policy that provides clear information for company representatives on what they can and cannot do in the clinical setting?

*\*\*Hospitals and other health care organizations should take note of the AdvaMed Code's revisions regarding representatives providing technical support in the clinical setting to understand how these revisions align with internal credentialing policies and requirements.*

New Section XIII of the AdvaMed Code provides high-level principles for **company representatives who provide technical product support**. Training and communication on these principles is important for representatives that enter the clinical setting, if applicable.

## ENSURE EVALUATION AND DEMO PROCEDURES INCORPORATE CONTROLS

- Do your policies address transparency requirements for providing evaluation equipment?
- What process do you have in place to analyze the length of an evaluation period and the appropriate amount of evaluation product?
- Does your company offer consignment product? Do you have the right controls in place?

*\*\*Hospitals and other health care organizations that receive evaluation, demonstration or consignment product should consider reviewing their own internal policies that govern these interactions.*

AdvaMed has updated Section XII of the Revised AdvaMed Code to incorporate additional clarity on transparency requirements and to include new information about the **treatment of consignment products under the Code**. See Revised AdvaMed Code, § XII.

## CONSIDER A COMPREHENSIVE, THIRD-PARTY ASSESSMENT OF YOUR COMPLIANCE FUNCTION

- Does your compliance organization align with the elements of an effective compliance program (as described in Section I of the Revised AdvaMed Code)?
  - Necessary oversight?
  - Appropriate Board-reporting infrastructure?
  - Policies, internal risk assessment, communication, training, corrective action, etc.?
- Is your compliance organization appropriately tailored to the size and scope of your business?

*\*\*Periodically engaging a third party to complete an **objective assessment of your compliance program** and structure can help enhance your program and keep it current. See Revised AdvaMed Code, § I.*

Is your compliance program tailored to past risks or have you considered potential future issues that may impact medical technology organizations:

- Asset Management
- Corporate Social Responsibility
- Health Economics
- Patient Interactions/Advocacy
- Product Pricing Issues
- Supply Chain Licensure
- Transparency/Reporting Obligations
- Value-Based Care

For more information, please contact **Matthew Wetzel** at +1 202.887.4221 or [mwetzel@akingump.com](mailto:mwetzel@akingump.com).