AdvaMed U.S. Code of Ethics Refresh 2020

BACKGROUND & PROJECT GOALS

Background/Timeline:

- ✓ Original AdvaMed Code launched in Sept. 2003 (formerly HIMA Code, eff. Jan. 1993)
- ✓ Revised & Restated AdvaMed Code launched in July 2009
- ✓ In the intervening 10 years:
  - New government guidance; informative settlements & enforcement actions
  - AdvaMed issued additional guidance on critical topics (e.g. transparency, PODs)
  - Other life sciences associations launched and revised their own codes
  - AdvaMed launched AdvaMed Code in China in 2016

Goals:

- ✓ Update language to address Code challenges, reflect evolving standards & business models
- ✓ Integrate existing AdvaMed guidance, where appropriate
- ✓ Bring FAQs & examples current
- ✓ Improve readability & user friendliness in mobile environment

PROCESS

- ✓ Formed working group of 55+ attorneys and compliance officers to draft updates
- ✓ Collected feedback from stakeholders (physicians, medical societies, medical colleges/hospitals, supply chain organizations, sales organizations, former prosecutors)
- ✓ Internal AdvaMed governance process to vet, review, and approve Code revisions
- ✓ December 2018: Approved updated Code and notified the public
- ✓ January 1, 2020: Effective date of revised Code

NEXT STEPS IN 2019

- ✓ Work with graphic artist on appearance
- ✓ Address Code enforcement or adjudication
- ✓ Finalize new FAQs & updated resources
- ✓ Evaluate Code certification and logo program
- ✓ Launch Code training program
- ✓ Develop small company resources
- ✓ Issue additional communications
- ✓ Benchmarking surveys
- ✓ Best practice discussions

OVERVIEW OF CHANGES

Overall Enhancements:

- ✓ Adds Cover Page, Table of Contents, & Glossary
- ✓ Adds "Key Concepts" sections with top-level takeaways
- ✓ Adds visuals, graphics, and callout boxes
- ✓ Adds examples, explanations, and FAQs

Introduction:

- ✓ Consolidates Preamble and Code Compliance
- ✓ Adds new Code "values" – Innovation; Education; Integrity; Respect; Responsibility; & Transparency
- ✓ Adds compliance program graphic depicting OIC/DOJ guidance
- ✓ Enhanced Definitions: Commercial Sponsorship; Educational Grant; Satellite Symposium; Third-Party Program; Organizer; Medical Technologies; Healthcare Practitioner (HCP)

Consulting:

- ✓ Adds examples of "legitimate need" to include training HCPs on the technical components of safely and effectively using a product; clinical expertise in conducting product research and

development; and a physician's expert judgment on clinical issues associated with a product
- ✓ Clarifies that different methods may be used to establish "fair market value," including third-party vendors or other experts' assistance
- ✓ Explains that the Code restricts sales reps' involvement to avoid the perception and risk that arrangements were made to reward purchasing, using, or recommending their device
- ✓ Highlights that physicians may have conflicts of interest that require mitigation
- ✓ Emphasizes the confirmation of services in accordance with the written agreement

Jointly Conducted Education & Marketing:
New section on jointly conducted education and marketing programs (legitimate need; controls; balanced content between HCP and company; equitable contributions towards activity and cost; subject to written agreement)

Travel:
Consolidates existing travel guidance, provides clarification on when travel is permitted (consulting, training, legitimate meeting, need for HCP presence) and when travel is prohibited (general education; attending Third-Party Programs; no legitimate need); includes additional information on evaluating appropriate venues for meetings (central location, conducive to exchange of information, limits on top category or luxury hotels)

Meals:
Consolidates guidance on meals into one section, adds on meal policies & benchmarking

Branded Promotional Items; Entertainment & Recreation; Providing Coverage, Reimbursement & Health Economics Information:
minimal revisions

Company Programs:
Consolidates existing sections on company-conducted training & education and other business meetings, explaining parameters for all such programs

Third-Party Programs:
Merged existing sections on providing support for third-party educational, charitable, and research programs into a comprehensive section:
- ✓ Educational Grants — Focus on meeting third-party organizer / accreditation standards; allow grant funds to be used by the organizer to provide items permissible under the Code; adds checklist of review questions to evaluate requests
- ✓ Commercial Sponsorship — Prohibits companies from passing to an HCP any benefits the company might receive in exchange for commercial sponsorship (ex: golf outing)
- ✓ Satellite Symposia – Clarifies that companies can host satellite symposia only under the Code's guidance for company-sponsored events
- ✓ Research Grants – Expands criteria to include requiring grant requests to contain clear documentation on the scope, budget, duration, and requirements for independent approvals; allowing in-kind or monetary support for legitimate, documented, study-related expenses and reasonable quantities of no-charge product; and recipients' independent control over results
- ✓ Charitable Donations – Expands criteria to allow charitable support through product donation and commercial sponsorship, restrict paying for HCPs' tickets to attend events, and guidance on company due diligence

Communications & Technical Support:
New sections
- ✓ Communicating for the safe and effective use of medical technology (principles for communicating on unapproved/uncleared uses; information provided by authorized personnel; clear indication of off-label; controls and polices on the issue based on existing guidance)
- ✓ Principles for company representatives providing technical support in the clinical setting (supervisory role of HCPs; transparency regarding role as company personnel; prohibition on interference with HCP decision making; patient privacy; credentialing; overhead expense)

Demonstration & Evaluation Product:
Clarifies acceptability of providing both single-use and multiple-use evaluation products at no charge for HCPs to assess the appropriate use of the product; notes transparency requirements; adds language on consignment products and recommendations for controls