

OVERVIEW OF CHANGES

Overall Enhancements:

- ✓ Adds a Cover Page, Table of Contents, and Glossary
- ✓ Adds “Key Concepts” at the beginning of each section to highlight top-level takeaways
- ✓ Adds visuals, graphics, and callout boxes
- ✓ Adds examples, explanations, and FAQs

Introduction:

- ✓ Consolidates existing Preamble and Code Compliance section into new Introduction
- ✓ Adds new Code “values” – Innovation; Education; Integrity; Respect; Responsibility; & Transparency
- ✓ Adds graphic on effective compliance program, citing Sentencing Guidelines & OIG/DOJ guidance
- ✓ New defined terms: Commercial Sponsorship; Educational Grant; Satellite Symposium; Third-Party Program; Third-Party Program Organizer
- ✓ Enhanced definitions: Medical Technologies; HCP

Consulting:

- ✓ Content remains primarily the same
- ✓ Adds clarifying language on “legitimate need”
- ✓ Includes callout explanation of how to develop a fair market value methodology
- ✓ Explains why sales’ role is limited under the Code
- ✓ Adds callout box highlighting that physicians may have conflicts of interest that require mitigation
- ✓ Includes language requiring confirmation of services in accordance with agreement

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

Third-Party Programs: Merged existing sections on providing support for third-party educational, charitable, and research programs into one comprehensive section on grants, donations, and commercial sponsorships

- ✓ Educational Grants – focus on meeting third-party organizer / accreditation standards; adds language that grant funds can be used by the organizer to provide items permissible under the Code (but not items impermissible under the Code); adds checklist of review questions for use in evaluating requests
- ✓ Commercial Sponsorship – Includes language that prohibits companies from passing along to an HCP any benefits the company might receive in exchange

for the commercial sponsorship (ex: golf foursome)

- ✓ Satellite Symposia – Adds language on whether companies can host satellite symposia and whether they can pay for HCPs’ travel costs associated with serving as faculty or with attending the program
- ✓ Research Grants – Expands and clarifies requirements for supporting independent research grant requests
- ✓ Charitable Donations – Expands and clarifies parameters for providing charitable donations

Jointly Conducted Education & Marketing: New section on jointly conducted education and marketing programs (legitimate need; controls; content should be balanced 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 need for meeting, HCP presence) and when travel is prohibited (general education; attending Third-Party Program; 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 language encouraging companies to develop meal policies & to review benchmarking information

Communications & Technical Support: New sections:

- ✓ Communicating for the safe and effective use of medical technology (i.e. principles for communicating on unapproved/uncleared uses – truthful & non-misleading; information provided by authorized personnel; identify information as off-label when communicating; develop controls and polices on the issue based on existing guidance)
- ✓ Principles for company representatives providing technical support in the clinical setting (direction/supervision of HCP; company personnel should be transparent that they are acting on behalf of company; cannot interfere with HCP decision-making; patient privacy; credentialing; cannot eliminate overhead expense)

Demonstration & Evaluation Product: Enhances existing language with clarity on when it is acceptable to provide evaluation products and contents of evaluation agreement; adds language that companies should be mindful of transparency requirements; adds language on consignment products and recommendations for controls

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