ReedSmith

The business of relationships.

COMPARISON CHART:
ADVAMED CODE (2005), REVISED ADVAMED CODE (EFF. 7/1/2009) AND REVISED PHRMA CODE (EFF. 1/1/2009)

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (eff. 7/1/2009)[2]	Revised PhRMA Code (eff. 1/1/2009)
I. Preamble	1. General. Notes that adoption of the AdvaMed Code is to facilitate Members' ethical interactions with Health Care Professionals ("HCPs"). 2. HCP Interactions. Describes different types of Member and HCP interactions, including: a. Advancement of medical technology; b. Safe and effective use of medical technology; and c. Research and education. 3. Effective Date. Includes effective date (January 1, 2004). 4. Interpretive Standard. States the standard that should be applied if the Code does not address a specific type of interaction: "Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful	***The revised AdvaMed Code's preamble has been expanded from the original, and now contains three distinct subheadings: (1) Medical Technologies; (2) Interactions with Health Care Professionals; and (3) The Purpose of the Code of Ethics.*** 1. **Medical Technologies. Distinguishes between (1) Medical Technologies,[3] which are dependent upon hands-on HCP interaction, and (2) drugs and biologics, which achieve their principal intended action by pharmacological, immunological or metabolic means.** 2. Interactions with HCPs. Describes different types of Company[4] and HCP interactions, including: **a. Promote** the Advancement of Medical Technologies, **b. Enhance** the Safe and Effective use of Medical Technologies, **c. Encourage** Research and Education; and **d. Foster Charitable Donations and Giving.** 3. The Purpose of the Code of Ethics. To ensure HCP-Company Collaborative relationships meet high ethical standards. 4. **Footnote. Notes that the principles of the Code are derived from the federal Anti-Kickback Statute, among other authorities. In addition, throughout the Code, reference to "unlawful inducement" reflect the Anti-Kickback Statute prohibitions.**	1. General. The revised PhRMA Code does not include extensive background on the pharmaceutical industry. However, similar to the current AdvaMed Code, it focuses on ethical relationships with HCPs. 2. HCP Interactions. States that the focus of the Code is on interactions with HCPs that relate to the marketing of products. States that interactions with HCPs are important to enable companies to: a. Inform HCPs about the benefits and risks of products; b. Provide scientific and educational information; c. Support medical research and education; and d. Obtain feedback/advice about products through consultation. 3. Effective Date. Effective date is January 1, 2009.

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1 Based on subject headings in the revised AdvaMed Code.

2 Revisions to the AdvaMed Code appear in **bold.**

3 The revised AdvaMed Code replaces the term "product" with the defined term, "Medical Technologies." Specifically, the revised Code defines "Medical Technologies" to include "medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities."

4 All references to "Members" in the revised AdvaMed Code have been changed to "Companies."

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	inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products." 5. Definition of HCPs. FAQs 2 & 3 define HCPs to include "individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Members' medical technology products in the United States." This further includes clinical and non-clinical people, decision-makers within GPOs, and any other people in a position to make product-related decisions, such as hospital purchasing agents, and physician practice managers. 6. Modest, Occasional, Hospitality. The current AdvaMed Code defines "modest" to mean moderate or low value (depending upon regional differences) and "occasional" to mean infrequent. "Hospitality" (undefined) should be modest and occasional.	5. Effective Date. Effective date is July 1, 2009. 6. Interpretive Standard "Note". Moved to new Section II (described below). 7. Definition of HCPs. Defined substantially the same as in the original AdvaMed Code; however, the revised Code broadens the definition of HCPs to include any individuals or entities "**involved in the provision of health care services and/or items to patients."** Like the original Code, HCPs include those individuals who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies. **Includes (in FAQ 2) persons who provide services (licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease or recommend Medical Technology** (*e.g.*, purchasing agents, practice managers, and GPO management). 8. Preamble and General FAQs. • FAQ 7: Modest, Occasional, Hospitality. **The revised Code removes use of the word "Hospitality" from the Code. The revised Code now reads in terms of modest meals and refreshments instead of "hospitality." FAQ 7 indicates that meals and refreshments should be modest.** FAQ 7 defines "modest" as moderate value**,** accounting for regional differences and "occasional" (infrequent). **FAQ 7 also states that Companies should consider establishing limits on frequency and costs of meals to comply with requirements that they be modest and occasional.** • FAQ 8: Employee Payment for Meals and Refreshments. **New FAQ 8 provides that a Company's employee or agent cannot pay for meals or refreshments for an HCP, even if out of pocket. However, the FAQ notes, there may be situations where an employee or agent may engage in certain activities with an HCP so long as the HCP and the employee or agent each pays his/her own way.**	
II. Code Compliance (AdvaMed) **Adherence to**	1. Code Compliance. The current AdvaMed Code states that Members will communicate the Code's principles to employees, agents, dealers and distributors with the expectation that they will adhere to the Code.	***This is a new section to the AdvaMed Code; Companies are "strongly encouraged" to adopt the Code.*** 1. Code Compliance. **Companies are strongly encouraged to adopt the Code and implement an effective compliance program to foster compliance with the Code.**	The revised PhRMA Code is generally consistent with the revised AdvaMed Code in this regard, with some exceptions. 1. Code Adherence. All companies that interact with HCPs about pharmaceuticals **should adopt**

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Code (PhRMA)		2. Certification. **Companies that adopt the revised Code are strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the revised Code and implemented an effective compliance program (signed by the CEO and Chief Compliance Officer or individuals with equivalent responsibilities). AdvaMed will publish (on its website) a list of Companies that have submitted the annual certification.** 3. Compliance Contact Information. **Companies that are AdvaMed members must (and non-members may) provide contact information for their compliance department or anonymous hotline to facilitate reporting violations. AdvaMed will publish this information on its website.** 4. Elements of Compliance Program. **Companies are strongly encouraged to follow the seven elements of an effective compliance program:** **a. Written policies and procedures;** **b. Compliance officer and committee;** **c. Effective training and education;** **d. Effective lines of communication (including an anonymous reporting function);** **e. Internal monitoring and auditing;** **f. Enforcement through well-publicized disciplinary guidelines; and** **g. Prompt response to problems and corrective action.** 5. "Note." Includes a similar standard as original Code: "Members shall encourage ethical business practices and socially responsible industry conduct and shall not **engage in any unlawful inducement**."	procedures to assure adherence to this Code. 2. Certification. Companies that publicly announce their commitment to abide by the Code and that complete an annual certification (signed by the CEO and Chief Compliance Officer) that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site. 3. Compliance Contact Information. Public website will provide contact information for Chief Compliance Officers. Comments received by PhRMA relating to a company's observance of the Code or conduct addressed by the Code will be referred by PhRMA to the company's Chief Compliance Officer. 4. External Verification of Compliance. PhRMA encourages members to seek external verification periodically (i.e., at least every three years) that they have policies and procedures in place to foster compliance with the Code. (PhRMA intends to issue general guidance for external verification and will identify on its web site if a company has sought and obtained verification of its compliance policies and procedures from an external source.)

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III. Company-Conducted Product Training and Education	Existing title for this section is "Member-Sponsored Product Training and Education." 1. Definition of Training. None. 2. Need for Training. Indicates that the FDA mandates training and education to facilitate the safe and effective use of medical technology. 3. Standards on Training: a. Must be conducted in clinical, educational, conference or other settings, including hotel or other meeting facilities conducive to the effective transmission of knowledge. b. Hands-on training should be held at training facilities, medical institutions, laboratories, or other appropriate facilities with training staff that have proper qualifications and expertise. c. Hospitality for attendees is permissible in the form of modest meals and receptions (modest in value, subordinate in time and focus to the educational or training purpose of the meeting). d. Payment for reasonable travel and modest lodging costs by attendees is permitted. e. Payment for meals, hospitality, travel or	***This revised section of the AdvaMed Code primarily serves to clarify the existing Code provision on Company-sponsored product training and education.*** 1. Definition of Training and Education. **Defines "training" as "training on the safe and effective use of Medical Technologies" and "education" as "communicating information directly concerning or associated with the use of Companies' Medical Technologies" (*e.g.*, disease states, patient benefits). Includes, for example, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds.** 2. Need for Training. Indicates that the FDA mandates training and education to facilitate the safe and effective use of Medical Technology. 3. Standards on Training. **Refines standards on training and education:** a. Must be conducted in a setting that is conducive to the effective transmission of information. Such settings may include clinical, educational, conference or other settings, including hotels or other meeting facilities **(this can include training and education at the HCP's site)**; b. Hands-on training should be held at training facilities, medical institutions, laboratories, or appropriate facilities with training staff with appropriate qualifications and expertise **(this can include qualified field sales employees with necessary technical expertise)**; c. Modest **meals and refreshments are permissible so long as subordinate in time and focus to the training or educational purpose;** d. Payment for out-of-town travel **(to efficiently deliver Training and Education on Medical Technologies)** is permitted **where the need is supported by objective reasons**. e. Payment for meals, **refreshments**, travel or other expenses of guests of HCPs or any other person without a *bona fide* professional interest in the information being shared is not permitted.	No comparable provision.

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	other expenses of guests of HCPs or any other person without a *bona fide* professional interest in the information being shared is not permitted.		
IV. Supporting Third-Party Educational Conferences	1. Types of Conferences. Conferences sponsored by national, regional, or specialty medical associations; conferences sponsored by accredited continuing medical education ("CME") providers; and grand rounds. 2. Types of Conference Support. a. Educational grants to conference sponsors to reduce conference costs, or to training institutions to permit attendance by students, residents, fellows: • training institution must select attendees; and • sponsor must control content, faculty, materials. b. Modest meals and hospitality may be provided to conference sponsor or Member may provide meals and receptions for all HCP attendees if consistent with sponsor's guidelines. c. Meals, receptions and hospitality must be modest in value and subordinate in time and focus to the conference. d. Grants to conference sponsors for faculty	***The revised Code provisions are generally consistent with the existing Code, however, the revised AdvaMed Code provides more clarification than the existing Code concerning entertainment and the prohibition against paying HCPs directly.*** 1. Types of Conferences. *Bona fide* independent, educational, scientific and policy making conferences typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited CME providers primarily dedicated to promoting objective scientific and educational activities and discourse. **(Grand rounds moved to Section III, "Company-Sponsored Product Training and Education.")** 2. Types of Conference Support. a. Conference Grants. May be provided to conference sponsors to reduce conference costs or to training institutions to permit attendance by students, residents, fellows and other HCPs in training: • gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; • training institution or conference sponsor must select attendees; • paid only to organizations with a genuine educational function; • **grants should be consistent with sponsor's standards and standards established by accrediting body; and** • sponsor must **independently** control content, faculty, materials**.** b. **Conference Meals and Refreshments. Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to attendees.**	The revised PhRMA Code includes two separate but related discussions of support for conferences. The first addresses third-party scientific and educational conferences and is generally consistent with the revised AdvaMed Code. The second is a more detailed discussion of support for third-party, accredited CME events. 1. Recipient. Any financial support should be given to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fees for all participants. 2. Travel, Lodging, Other Personal Expenses. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty HCPs attending third party scientific and educational conference or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor. 3. Compensation for Time. Funding should not be offered to compensate for the time spent by HCPs attending the conference or meeting. 4. Control over Content. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational

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	expenses including honoraria, travel, lodging and meals. e. Advertisements and demonstrations for Member displays.	**Companies may provide meals and refreshments if: (1) provided to all HCP attendees (with one exception) and (2) provided in a manner consistent with sponsor's and accrediting body's standards. Meals and refreshments can be provided to fewer than all attendees if the Company satisfies all other principles related to meals set forth in Section VIII.** Meals and **refreshments** should be modest in value, subordinate in time and focus to the purpose of the conference, **and clearly separate from CME portion of program.** c. Faculty Expenses. Grants to conference sponsors for *bona fide* faculty members' expenses including honoraria, travel, lodging and meals. d. Advertisements and Demonstration. Companies may purchase advertisements and lease booth space for Company displays. 3. Sales Meetings at Third-Party Educational Conference. **FAQ 21 permits a Company to sponsor an off-site sales, promotional or other business meeting that is ancillary to a third-party educational conference, provided that there is a legitimate business purpose and the Company complies with the conference sponsor's guidelines.**	methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. 5. CME-Specific Provisions. a. A CME provider can—at its own discretion—apply financial support provided by a company for meals for all participants. Companies cannot provide meals directly at CME events. FAQ states that meals can be provided if separate from CME and consistent with sponsor guidelines. b. Companies should separate CME grant-making functions from sales and marketing departments. c. Develop objective criteria for making CME grant decisions. d. Companies should follow the standards for commercial support established by the Accreditation Council for continuing Medical Education ("ACCME") or other entities that accredit the CME. 6. Types of Non-CME Third-Party Conferences. Revised PhRMA Code allows support for third-party scientific and educational conferences or professional meetings, defined as "any activity, held at an appropriate location, where (a) the gathering is primarily dedicated . . . to promoting objective scientific and educational activities . . . and (b) the main incentive . . . is to further [attendees'] knowledge on the topic(s) being

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			presented."
V. Sales, Promotional and Other Business Meetings (AdvaMed term) **Informational Presentations (PhRMA term)**	1. Meeting Topics. Members may meet with HCPs to discuss product features, contract negotiations, and sales terms. 2. Meals, Receptions. Permits Members to provide occasional modest meals and receptions that are conducive to the exchange of information. 3. Travel Costs. Members can pay reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment). 4. HCP Guests. No meals, hospitality, travel or lodging for HCP guests or those not having *bona fide* professional interest.	***This section of the revised AdvaMed Code has not been changed substantially.*** 1. Meeting Topics. Companies may meet with HCPs for a variety of sales, promotional and other business purposes, to discuss for example, Medical Technology features, sales terms, or **contracts.** 2. Meals, **Refreshments.** Permits Companies to provide occasional **modest meals and refreshments**. 3. Travel Costs. Companies can pay reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment). 4. HCP Guests. No meals, **refreshments**, travel or lodging for HCP guests or those not having *bona fide* professional interest. Note: Meals are also discussed in Section VIII.	There is no direct counterpart in the revised PhRMA Code; but, the PhRMA Code addresses Informational Presentations. 1. Meals. Modest and occasional meals can be offered in connection with informational presentations by representatives and others speaking on a company's behalf so long as: a. Limited to in-office or in-hospital settings if made by sales representative or immediate manager; b. Not part of entertainment or recreation; and c. Conducive to informational communication. 2. No Dine & Dash, Take-Out. No "dine & dash" or take-out meals or meals without a company representative. 3. HCP Guests. No spouses or other guests.
VI. Consulting Arrangements with Health Care Professionals	1. General. Appropriate to pay HCPs reasonable compensation for providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration. 2. Standards. Factors that support the existence of a *bona fide* consulting	***This section of the revised AdvaMed Code expands on the original version. In particular, it contains a new section addressing royalty arrangements.*** 1. General. Appropriate to provide **fair market value** ("FMV") compensation for services intended to fulfill a legitimate business need **and do not constitute an unlawful inducement**. 2. Standards. **Compliance standards associated with consulting arrangements**: a. Should be written and describe all services to be provided **(for clinical research services,**	Unlike the revised AdvaMed Code, the PhRMA Code does not address royalty arrangements. 1. General. Appropriate to provide reasonable compensation for services and reimbursement for reasonable travel, lodging, and meal expenses incurred in providing consulting services. 2. Standards. Factors that support a *bona fide*

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	arrangement between Members and HCPs include: a. Written arrangements signed by the parties specifying the services provided; b. Compensation consistent with FMV for the service provided; c. Legitimate need for the services and purpose for the services identified in advance; d. Selection of consultants based on qualifications and expertise, not on volume or value of business; e. Venue and circumstances for meetings should be appropriate to subject matter and conducted in clinical, educational, conference or other setting (including hotel or other commercial facility) conducive to the exchange of information; f. Member-sponsored hospitality should be modest in value and subordinate in time and focus to the purpose of the meeting; g. Members may pay for reasonable and actual expenses, including travel, modest meals, and lodging costs incurred by consultants attending meetings with, or on behalf of,	**must have a written research protocol)**; b. Should be legitimate need for the consulting services, which is identified in advance of **the services and documented**; c. Selection of consultants should be on the basis of the consultant's qualifications and **expertise to meet the defined need**; d. **Compensation should be consistent with fair market value in an arm's length transaction and should not be based on the volume or value of a consultant's past, present or anticipated business;** e. Companies may pay for **documented,** reasonable and actual expenses, including reasonable and actual travel, modest meals and lodging costs; f. Venue and circumstances for Company meetings with consultants should be appropriate to subject matter and conducted in clinical, educational, conference or other setting (including a hotel or other commercial facility) conducive to the exchange of information; g. Company-sponsored **meals and refreshments** should be modest in value and subordinate in time and focus to the purpose of the meeting **(no recreation or entertainment may be provided)**. h. **Sales personnel may provide input about the suitability of a proposed consultant but should not control or unduly influence the decision of whether to engage a particular HCP as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this provision.** 3. **<u>Royalties</u>. New section on royalty payments:** **a. Arrangements involving royalties paid to an HCP should meet the contractual standards above.** **b. Royalty arrangements should be entered only where the HCP is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of**	consulting agreement: a. Written contract specifies the nature of the consulting services and the basis for payment. b. Legitimate need for the consulting services identified in advance of requesting the services. c. Criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular HCPs meet those criteria. d. Number of HCPs retained is not greater than the number reasonably necessary to achieve the identified purpose. e. Company maintains records concerning and makes appropriate use of the services provided by consultants. f. Venue and circumstances of any meeting with consultants are conducive to services and activities related to the services are the primary focus of the meeting (resorts are not appropriate venues). g. Modest meals or receptions may be appropriate during company-sponsored meetings with HCP consultants. h. No recreational or entertainment events in

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	Members. h. There should be a written research protocol for research services.	**a product, technology, process, or method.** **c. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.** **d. Calculation of royalties should be based on factors that preserve the objectivity of medical decision-making and avoid improper influence. For example, royalties should not be conditioned on (i) a requirement that the HCP purchase, order or recommend any product or Medical Technology of the Company or any product or technology produced as a result of the project, or (ii) a requirement to market the product or medical technology upon commercialization.** **e. Companies can enter separate consulting agreements with HCPs (to whom they pay royalties) for marketing services if the services meet the requirements of Consulting Arrangements described above.** **f. Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from royalty calculations the number of units of a product purchased, used or ordered by the HCP or his/her practice group.** 4. **NEW/REVISED FAQs:** **a. Company should hire only as many consultants as are "necessary to fulfill" the Company's requirements for *bona fide* services (FAQ 26).** **b. The AdvaMed Code's restrictions apply to interactions with consultants in the same way as they do for interactions with other HCPs (FAQ 30).** **c. Defines consulting arrangement as any relationship in which services are provided to a Company by an HCP in exchange for remuneration (FAQ 31).** **d. Examples of consulting arrangements include education and training services, speaking engagements, proctoring and preceptorships, reference center or center of excellence relationships, advisory boards and focus groups, product development and research service, arrangements for the development or transfer of intellectual property (FAQ**	conjunction with HCPs serving as consultants. i. Compensation and reimbursement should be reasonable and based on fair market value. j. Decisions regarding the selection or retention of HCPs as consultants should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. k. Companies should not use consultant arrangements as inducements or rewards for prescribing a particular medicine or course of treatment. l. No honoraria, travel or lodging expenses to non-consultant HCP attendees at company-sponsored meetings, including attendees who participate in interactive sessions.

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		31). **e. Selection of consultants must be based on qualifications and expertise to meet a defined need, and this may include, among others, experience with, or usage of, or, familiarity with a specific Medical Technology (FAQ 32). However, neither selection nor compensation should be to reward past usage or constitute an unlawful inducement.** **f. Establishing FMV may include a variety of methods, but in all cases, FMV should be established with objective, verifiable criteria and methodology should be documented (FAQ 34).** **g. Criteria for "legitimate need" for consultant services are separate from generating business, and typically exist if a consulting arrangement would have been entered into absent the opportunity to generate business directly from the HCP who will be serving as the consultant (FAQ 35).**	
VII. Prohibition on Entertainment and Recreation	No comparable provision.	***This is a new section of the AdvaMed Code.*** 1. **Companies should not provide or pay for any entertainment or recreational events or activities for non-employee HCPs.** 2. **Examples include theater, sporting events, golf, skiing, hunting, sporting equipment and leisure or vacation trips.** 3. **Entertainment and recreational items should not be provided regardless of (a) their value, (b) whether the HCP is a speaker or consultant, or (c) whether the entertainment is secondary to an educational purpose.** 4. **New FAQ 36 notes that the restriction applies to a Company's employee or agent, even if the employee pays. There may be situations where an employee or agent can engage in certain activities with an HCP if each pays his/her own way.**	The revised PhRMA Code is generally consistent with the revised AdvaMed Code in this regard**.** 1. Companies should not provide any entertainment or recreational items. 2. Entertainment or recreational benefits should not be offered regardless of (a) the value of the items, (b) whether the HCP is a speaker or consultant, or (c) whether the entertainment or recreation is secondary to an educational purpose. 3. Permits modest occasional meals offered in appropriate circumstances and venues.

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VIII. Modest Meals Associated with Health Care Professional Business Interactions **(AdvaMed term)** **Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals** **(PhRMA Term)**	1. Current AdvaMed Code states that Members can pay for modest meals that are conducive to the exchange of information at a sales and promotional meeting. 2. No meals for guests of HCPs or other persons who do not have a *bona fide* professional interest in the information being shared at the sales and promotional meeting.	***This is a new section of the AdvaMed Code, which addresses the provision of meals associated with various HCP interactions.*** 1. **Modest meals may be provided as an occasional business courtesy in connection with business interactions with HCPs that involve the presentation of scientific, educational or business information.** 2. **<u>Purpose</u>. The meal should be incidental to the *bona fide* presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.** 3. **<u>Setting and Location</u>. Meals should be offered in a setting conducive to *bona fide* scientific, educational or business discussions. Meals may occur at the HCPs site. However, if such site is not conducive to exchange of information or is impractical or inappropriate, meals may be provided off-site, for example (1) Medical Technology cannot easily be transported to the HCP's location; (2) confidential product development or improvement information is being discussed; or (3) a private space cannot be obtained.** 4. **<u>Participants</u>. Meals can only be provided to HCPs who actually attend; no meals for office staff where everyone does not attend. No "dine and dash" or take out. No meals for guests of HCPs or any other person without a *bona fide* professional interest in the information.** 5. **<u>Other Principles</u>. Additional principles from other sections of the Code may apply depending upon the business interaction or meeting.** 6. **FAQ 37 indicates that a business presentation includes substantial discussion of product development/improvement, pricing, contract negotiation. Development of good will and business relationships should not be the primary purpose.**	The revised PhRMA Code is similar to the revised AdvaMed Code, but the circumstances under which off-site meals are permitted vary. 1. Meals can be offered in connection with informational presentations by representatives and others speaking on a company's behalf if: a. Occasional; b. Not part of entertainment/recreational event; c. Conducive to informational communication; and d. Modest as judged by local standards 2. Meals in connection with informational presentation by sales representatives or their immediate managers must be limited to the in-office or in-hospital setting—no meals at restaurants. (Note, however, that it appears that company representatives that are not sales personnel or managers may provide off-site meals.) 3. No spouses or other guests. 4. No "dine & dash" programs or take-out meals.

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IX. Educational Items: Prohibition on Gifts **(AdvaMed term)** **Prohibition of Non-Educational and Practice Related Items and Educational Items** **(PhRMA Terms)**	1. Patient Benefit, Educational Function. Permits modest gifts to HCPs if gifts benefit patients or serve a genuine educational function. 2. $100 Cap. Any gifts should have a FMV of less than $100 unless medical textbook or anatomical model used for educational purposes. 3. Branded Items. Permits occasional gifts of branded promotional items of minimal value related to HCP's work or for the benefit of patients. 4. No Cash/Cash Equivalents. Gifts may not be given as cash or cash equivalents. 5. Food, Wine. Prohibits gifts of food or wine. 6. Gifts to Office Staff. Prohibits gifts such as flowers, gift baskets, meals, snacks, wine or other refreshments to HCPs or HCP's office staff, because not considered related to HCP's work or for the benefit of patients. 7. Significant Life Events. Permits Members to provide a small gift (valued at less than $100) (flowers, fruit baskets) to an HCP upon a significant life event (*e.g.*, birth, death, serious illness).	***This section of the revised AdvaMed Code includes a new prohibition on branded, non-educational, non-patient benefit items, even if such items are of minimal value.*** 1. Patient Benefit, Educational Function. Permits Companies to occasionally provide modest **items** to HCPs that benefit patients or serve a genuine educational function. 2. $100 Cap. Any items should have a FMV of less than $100, except for medical textbooks or anatomical models used for educational purposes. 3. **HCP Benefit. No items intended for the non-educational or non-patient-related benefit of HCPs, office staff, or family/friends (*e.g.*, DVD player or MP3 player/I-Pod).** 4. Branded Items. **No non-educational, branded promotional items may be provided, even if the item is of minimal value and related to the HCP's work or for the benefit of patients (*e.g.*, pens, notepads, mugs, and other items with Company name, logo or logo of product).** 5. Food/Cash: No gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents. 6. Gifts to Office Staff. Revised FAQ 38 prohibits gifts such as flowers, gift baskets, meals, snacks, wine or other refreshments to HCPs or office staff because not considered educational or for the benefit of patients. **Revised FAQ 39 indicates that gifts to staff are treated under the Code the same as gifts to HCPs.** 7. Significant Life Events. **FAQ 40 prohibits Companies from giving flowers, fruit baskets, etc. to recognize HCP life events (wedding, birth, anniversary, death, etc.).** 8. Raffles. **FAQ 41 prohibits raffling off items (or giving such items away at a tradeshow) to HCPs that would otherwise be prohibited.** 9. Examples of Patient Benefit Items. **FAQ 42 provides examples of items intended for the benefit of patients (starter kits, educational brochures) and items that are not intended for the benefit of patients (scrubs, office supplies). FAQ 42 notes that with respect to starter kits, Companies should adopt appropriate safeguards to ensure they are not offered as an**	This section of the revised PhRMA Code generally mirrors the revised AdvaMed Code. 1. Patient Benefit. Appropriate to offer items designed primarily for the education of patients or HCPs 2. $100 Cap. Appropriate to offer items designed primarily for the education of patients or HCPs, if the items are not of substantial value ($100 or less) and do not offer value to the HCP outside of professional responsibilities (*e.g.*, an anatomical model is intended for patient education and is appropriate whereas a DVD or CD player may have independent value). These items should be offered only occasionally, even if each item is appropriate. 3. Branded Items. Not appropriate to provide items for the HCP's use that do not advance disease or treatment education, even if practice-related items of minimal value (*e.g.*, pens, notepad, mugs or other items with company or product logos). These items should not be offered to HCPs or staff. 4. No Items for Personal Benefit of HCP/Staff. No items intended for the personal benefit of HCPs (*e.g.*, floral arrangements, artwork, music CDs or tickets to a sporting event), even if provided with product information at the same time. No gasoline, golf balls, sports bags, etc. 5. Cash/Cash Equivalents. No cash or cash equivalents (*e.g.*, gift certificates), except as

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		unlawful inducement.	compensation for *bona fide* consulting or speaking services. 6. Samples. Appropriate to provide samples for patient use per the Prescription Drug Marketing Act.
X. Provision of Coverage, Reimbursement, and Health Economics Information	1. Provision of Reimbursement Information. Members may support accurate and responsible billing to Medicare and other payors by providing reimbursement information to HCPs. 2. Coverage, Coding, Billing Information. Information may be about Members' products, appropriate coverage, coding or billing of products, or procedures using those products. 3. Technical Support. Members may provide information that gives technical or other support intended to aid in the appropriate and efficient use or installation of the Member's products. Such support may not be to unlawfully induce HCPs to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of a Member's products.	***This section substantially expands and revises the AdvaMed Code and addresses more specific arrangements involving reimbursement support and related activities.*** 1. Accurate, Objective Information. Companies may provide accurate and objective, **timely and complete coverage, reimbursement and health economic information** on their products. 2. **Collaboration with Other Persons/Entities. Companies may collaborate with HCPs, patients and organizations that represent their interests, to achieve government and commercial payor coverage decisions, guidelines and policies, and adequate reimbursement levels that allow patients to access Medical Technologies.** 3. **Permissible Activities: Permissible activities identified include (but are not limited to):** **a. Identifying clinical value of Medical Technologies;** **b. Collaborating with HCPs and others to conduct joint advocacy on coverage, reimbursement and health economics issues;** **c. Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to HCPs regarding Medical Technologies, including identifying coverage, codes and billing options that may apply;** **d. Providing accurate and objective information on economically efficient Medical Technology use;** **e. Providing information on reimbursement revenues and costs;** **f. Providing information on changes to coverage or reimbursement amounts,**	No comparable provision; the revised PhRMA Code does not address reimbursement and health economic support.

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		methodologies and policies; **g. Providing accurate and objective information designed to offer technical and other support; and** **h. Facilitating access to Medical Technologies by assisting HCPs with obtaining patient coverage decisions from payors.** **i. This includes providing information and training on policies and procedures for obtaining prior authorization and providing sample letters and information on medical necessity and appeals of denied claims.** **ii. In addition, at the request of an HCP and subject to privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals; however, such assistance should not be provided as an unlawful inducement.** **i. Companies cannot interfere with an HCP's decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement (*e.g.*, providing a free service that eliminates an HCP's overhead or other expense). A Company should not suggest mechanisms for billing services that are not medically necessary or for engaging in fraudulent practices to achieve inappropriate payment.**	
XI. Research and Educational Grants and Charitable Donations	1. General. Permits donations for a charitable purpose, such as supporting independent medical research, indigent care, patient education, public education, or sponsorship of events where the proceeds are intended for charitable purposes. 2. Charitable Donations. Donations should be made only to charitable organizations or individuals engaged in charitable missions for	***This section of the revised AdvaMed Code expands the existing Code to provide more detail concerning the types of permissible grants and donations and applicable criteria.*** 1. General. Permits research and educational grants and charitable donations. 2. No Unlawful Inducement. Grants or donations may not be provided as an unlawful inducement. **Companies should implement procedures to ensure no unlawful inducement via grants and donations.** 3. Objective Grant Criteria. **Companies should (a) develop objective criteria for making grant and donation decisions that do not account for the volume or value of purchases made by**	1. Research. No separate section on research grants. 2. Charitable Donations. No separate section on charitable donations. FAQ states appropriate to make charitable contributions (*e.g.*, purchase table at a fundraising dinner or slot at a golf tournament) but cannot invite HCPs to attend. 3. Educational Grants. Educational grants covered as part of CME section. The revised PhRMA Code excludes sales and marketing personnel from CME

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	the support of that mission. 3. No Unlawful Inducement. Donations may not be made to unlawfully induce HCPs to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of Members' products. 4. Documentation. Donations should be appropriately documented. 5. Types of Grants. Examples of appropriate charitable grants include: a. Advancement of medical education of medical students, residents, and fellows; b. Support of research with scientific merit where the purpose of the grant is clearly documented; and c. Education of patients or the public about important health care topics.	**or anticipated from the recipient; (b) implement procedures to ensure grants and donations are not used as an unlawful inducement; and (c) ensure appropriate documentation of grants and donations.** 4. Sales Involvement. **Sales personnel may provide input about the suitability of grant or donation recipient or program, but may not control or unduly influence the decision of whether a particular HCP will receive the grant or donation or the amount. Companies should consider implementing procedures to monitor compliance with this provision.** 5. Research Grants. **a.** Companies may provide research grants to support **independent medical** research with scientific merit, with well-defined objectives and milestones, and no direct or indirect link to purchases. **New FAQ 49 prohibits unrestricted grants, stating that research must have defined goals, objectives, and milestones.** **b. Company-initiated or directed research involving a Company's Medical Technologies (*e.g.*, clinical studies) are addressed separately in Section VI (Consulting Arrangements).** 6. Educational Grants. Companies may provide educational grants for advancement of medical education and public education; **no grants may be given to individual HCPs**. 7. Charitable Grants. **a.** Company may make monetary or donations of Medical Technologies for charitable purposes **(such as supporting indigent care, patient education, public education or the sponsorship of events where proceeds are intended for charitable purposes).** **b.** Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations **or, in rare instances, to individuals engaged in charitable activities for the support of a *bona fide* charitable mission**. **c. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or mission. New FAQ 51 indicates that relevant factors include: (1) the entity's tax status; (2) the entity's corporate status under state law; and (3) whether**	grant-making functions. 4. Independence. General section on Independence and Decision-Making provides that grants, scholarships, subsidies, support, consulting contracts, and educational or practice related items should not be provided or offered to an HCP in exchange for prescribing products.

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		the organization has a charitable mission or purpose, among other factors. **d. New FAQ 50 permits contributions to charitable events such as golf tournaments or galas but states that Companies may not pay for individual HCPs to play or participate.**	
XII. Evaluation and Demonstration Products	No comparable provision.	***This is a new section to the AdvaMed Code.*** **1. <u>General.</u> Company products that may be provided to HCPs for evaluation include (a) single use products (consumable or disposable), and (b) multiple use products (capital equipment), provided at no charge to allow HCPs to assess the appropriate use and functionality and to determine whether/when to use, order, purchase or recommend the product. Products provided for evaluation are typically expected to be used in patient care.** **2. <u>Single-Use/Consumables/Disposables.</u> Number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation.** **3. <u>Multiple Use/Capital.</u> Multiple use products should be provided without transfer of title and should be furnished only for a period of time that is reasonable to allow an adequate evaluation. Terms should be set in advance in writing. Company should have process for promptly removing the product from HCP's location at the end of the evaluation period, unless HCP purchases or leases the product.** **4. <u>Demonstration.</u> These are typically unsterilized, single use products or mock-ups used for HCP and patient awareness, education and training. Demonstration products are not intended to be used in patient care and are typically identified as such ("Sample," "Not for Human Use," or other designation).** **5. <u>Documentation.</u> Companies should provide HCPs with documentation of the no charge status of evaluation and demonstration products.** **6. <u>Duration of Evaluation Period.</u> New FAQ 53 describes the factors to consider in calculating the length of time reasonably necessary for HCP to assess a multiple use product (*e.g.*, frequency of anticipated use, duration of required training, number of HCPs who will**	No comparable provision; the revised PhRMA Code does not address evaluation and demonstration products.

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		evaluate the product, and length of time to evaluate different product features, etc.).	

Prepared By: Elizabeth Carder-Thompson, ECarder@ReedSmith.com
Gina M. Cavalier, GCavalier@ReedSmith.com
Matthew E. Wetzel, MWetzel@ReedSmith.com

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