

## Attachment A

### Revisions to the PhRMA Code on Interactions with Healthcare Professionals<sup>1</sup>

	<u>Original PhRMA Code (2002)</u>	<u>Revised PhRMA Code (2008)</u>
<b>Promotional Materials</b>		<ul style="list-style-type: none"> <li>✓ Promotional materials should:               <ul style="list-style-type: none"> <li>(a) be accurate and not misleading;</li> <li>(b) only make substantiated claims;</li> <li>(c) reflect the balance between risks &amp; benefits; and</li> <li>(d) be consistent with all FDA requirements.</li> </ul> </li> </ul>
<b>Informational Presentations</b>	<ul style="list-style-type: none"> <li>✓ Occasional meals can be offered in connection with informational presentations by representatives and others speaking on a company's behalf if:               <ul style="list-style-type: none"> <li>(a) are modest as judged by local standards;</li> <li>(b) are not part of entertainment/recreational event;</li> <li>(c) are conducive to informational communication.</li> </ul> </li> <li>✓ No "dine &amp; dash" programs or take-out meals.</li> <li>✓ No spouses or other guests.</li> </ul>	<ul style="list-style-type: none"> <li>✓ Same as 2002 Code.</li> <li>✓ <b><i>NEW: 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.</i></b></li> </ul>
<b>Entertainment and Recreation</b>	<ul style="list-style-type: none"> <li>✓ No entertainment/recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion.</li> <li>✓ Entertainment/recreation is permissible where HCPs are providing legitimate consulting, advisory board, or speaker-training services.</li> </ul>	<ul style="list-style-type: none"> <li>✓ No entertainment or recreational items, including tickets to the theater or sporting events, sporting equipment, leisure or vacation trips.</li> <li>✓ No entertainment/recreation, even if the company engages the HCP as a speaker or consultant or the entertainment or recreation is secondary to an educational purpose.</li> <li>✓ Modest, occasional meals are permitted so long as they are offered in accordance with the Code.</li> </ul>
<b>CME Funding</b>	<ul style="list-style-type: none"> <li>✓ <u>Funding to CME Provider</u>. Financial support should be given to the CME provider.</li> <li>✓ <u>Content, Faculty, Materials</u>. Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers.</li> <li>✓ <u>Travel, Lodging, Other</u>. No financial support for the costs of travel, lodging, or other personal expenses of non-faculty HCPs attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor.</li> <li>✓ <u>Compensation for HCP Time</u>. No funding to compensate for the time spent by HCPs participating in the CME event.</li> <li>✓ <u>Meals</u>. Financial support may be provided to CME sponsors to cover the costs of meals or receptions. Alternatively, companies can provide meals or receptions directly at the event. Meals or receptions should be modest, conducive to discussion and amount of time at meals or receptions should be</li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Funding to CME Provider</u>. Same as 2002 Code.</li> <li>✓ <u>Content, Faculty, Materials</u>. Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines, <b><i>even if the Company's input is requested from the CME provider.</i></b></li> <li>✓ <u>Travel, Lodging, Other</u>. Same as 2002 Code.</li> <li>✓ <u>Compensation for HCP Time</u>. Same as 2002 Code.</li> <li>✓ <u>Meals</u>. <b><i>A CME provider can apply financial support provided by a company for meals for all participants; but, companies can no longer provide meals directly at CME events.</i></b></li> </ul> <p><u>OTHER NEW ITEMS:</u></p> <ul style="list-style-type: none"> <li>✓ <u>Separate Grant-Making from Marketing</u>. <b><i>Separate CME grant-making functions from sales and marketing departments.</i></b></li> <li>✓ <u>Grant-Making Criteria</u>. <b><i>Develop objective criteria</i></b></li> </ul>

<sup>1</sup> Additions to the Code are listed in ***bold and italics***.

	<b>Original PhRMA Code (2002)</b>	<b>Revised PhRMA Code (2008)</b>
	subordinate to time spent at the educational activities.	<i>for making CME grant decisions.</i> ✓ <b>ACCME Standards. Follow the standards for commercial support established by the Accreditation Council for continuing Medical Education (ACCME) or other entities that accredit the CME.</b>
<b>CME – Location</b>	<ul style="list-style-type: none"> <li>✓ A conference must be primarily dedicated to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering).</li> <li>✓ The main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.</li> </ul>	<ul style="list-style-type: none"> <li>✓ Notably, the revised Code is silent on location for CME events. It is reasonable to conclude that PhRMA’s approach is to allow the CME provider to choose the venue itself without input from the supporting company, regardless of where the venue is located.</li> </ul>
<b>Third-Party Educational or Professional Meetings</b>	<ul style="list-style-type: none"> <li>✓ The 2002 PhRMA Code uses “Continuing Medical Education” and “Third-Party Educational or Professional Meetings” interchangeably.</li> <li>✓ The same rules listed under the CME category apply to Third-Party Educational or Professional Meetings (i.e., non-CME-accredited events), per the 2002 Code.</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b><u>Definition.</u> The 2008 PhRMA Code defines a third-party scientific and educational conference or professional meeting as any activity held at an appropriate location where (a) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse and (b) the main incentive for bringing attendees together is to further their knowledge on the topic being presented.</b></li> <li>✓ <b><u>Financial Support to Sponsor.</u> Financial support should be given to the conference’s sponsor.</b></li> <li>✓ <b><u>Travel, Lodging, Other Costs.</u> 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.</b></li> <li>✓ <b><u>Compensation for HCP Attendance.</u> Funding should not be offered to compensate for time spent by HCPs attending the meeting.</b></li> <li>✓ <b><u>Control of Content.</u> Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.</b></li> <li>✓ <b><u>Meals.</u> Direct provision of meals at a third-party conference or professional meeting is permitted so long as the meals are modest and clearly subordinate to the amount of time spent at other aspects of the meeting.</b></li> </ul>
<b>Consultants</b>	<ul style="list-style-type: none"> <li>✓ Appropriate to provide reasonable compensation and reimbursement for reasonable travel, lodging, and meal expenses incurred in providing services.</li> <li>✓ No token consulting or advisory arrangements.</li> <li>✓ Factors of a bona fide consulting agreement: <ul style="list-style-type: none"> <li>○ written contract that specifies the nature of the consulting services and the basis for payment;</li> <li>○ legitimate need for the consulting services identified in advance of requesting the services;</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>✓ Same as 2002 Code.</li> <li><b><u>NEW:</u></b></li> <li>✓ <b><i>Modest meals or receptions may be appropriate during company-sponsored meetings with HCP consultants.</i></b></li> <li>✓ <b><i>No recreational or entertainment events in conjunction with HCPs serving as consultants.</i></b></li> <li>✓ <b><i>Compensation and reimbursement should be reasonable and based on fair market value.</i></b></li> </ul>

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	<ul style="list-style-type: none"> <li>○ criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have expertise necessary to evaluate whether the HCP meets criteria;</li> <li>○ number of HCPs retained is not greater than necessary to achieve the identified purpose;</li> <li>○ company maintains records concerning services provided by consultants;</li> <li>○ venue and circumstances of any meeting with consultants are conducive to services + activities related to the services are the primary focus of the meeting (no resorts).</li> </ul> <p>✓ No honoraria, travel or lodging expenses to non-consultant HCP attendees at company-sponsored meetings, including attendees who participate in interactive sessions.</p>	<p>✓ <b>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.</b></p> <p>✓ <b>Companies should not use consultant arrangements as inducements or rewards for prescribing a particular medicine or course of treatment.</b></p>
<b>Speaker Programs and Speaker Training Meetings</b>	<p>✓ Appropriate to provide reasonable compensation to HCPs who participate in programs intended to train speakers for company-sponsored programs.</p> <p>✓ Appropriate to provide speaker-trainers reimbursement for reasonable travel, lodging, and meal expenses.</p> <p>✓ Compensation and reimbursement should only be offered if:</p> <p>(1) the participants receive extensive training on the company's drug products or other specific topic to be presented and on compliance with FDA regulatory requirements for communications;</p> <p>(2) this training will result in the participants providing a valuable service to the company; and</p> <p>(3) the participants meet the general criteria for bona fide consulting arrangements.</p>	<p>✓ Same as 2002 Code.</p> <p><u>NEW:</u></p> <p>✓ <b>Hold training sessions in venues that are appropriate and conducive to informational communication and training about medical information (no resorts).</b></p> <p>✓ <b>Select and retain HCPs as speakers based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills.</b></p> <p>✓ <b>Speaking arrangements should not be inducements or remuneration for prescription or treatment decisions.</b></p> <p>✓ <b>Compensation &amp; reimbursement must be reasonable and fair market value.</b></p> <p>✓ <b>Cap total annual compensation paid to an individual HCP in connection with all speaking arrangements + develop policies on the use of speakers, including appropriate number of engagements for any one speaker over time.</b></p> <p>✓ <b>Speaker programs may include modest meals for attendees and should occur in a venue &amp; manner conducive to informational communication.</b></p> <p>✓ <b>Clarify to speakers that speaker programs are distinct from CME programs.</b></p> <p>✓ <b>Monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.</b></p>
<b>HCPs who are Members of Formulary or Clinical Practice Committees</b>		<p>✓ <b>Require any HCP who is a member of a formulary or clinical guideline committee and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of the relationship with the company.</b></p> <p>✓ <b>Disclosure should last at least two years after</b></p>

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		<p><i>termination of the speaker/consultant arrangement.</i></p> <p>✓ <b>Require HCPs who serve as speakers or consultants for companies to follow the committee's procedures, which may include recusal from decisions relating to the company's products.</b></p>
<b>Scholarship and Educational Funds</b>	<p>✓ Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other HCPs in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution.</p> <p>✓ "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policymaking meetings of national, regional, or specialty medical associations.</p>	<p>✓ Same as 2002 Code.</p>
<b>Educational and Practice-Related Items</b>	<p>✓ No items intended for the personal benefit of HCPs (such as floral arrangements, artwork, music CDs or tickets to a sporting event).</p> <p>✓ No payments in cash or cash equivalents (such as gift certificates), except as compensation for bona fide consulting or speaking services.</p> <p>✓ Appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.</p> <p>✓ No golf balls or sports bags.</p> <p>✓ No items such as gasoline intended for the personal benefit of an HCP, even if provided with product information at the same time.</p> <p>✓ Stethoscopes are permitted because they are provided for the patient's benefit.</p> <p>✓ A gift certificate redeemable solely for a medical textbook or a book on patient care is acceptable so long as not for substantial value.</p> <p>✓ Appropriate to provide items of minimal value if they are primarily associated with an HCP's practice (such as pens, notepads, and similar "reminder" items with company or product logos).</p> <p>✓ Appropriate to provide items primarily for the benefit of patients if \$100 or less (e.g., an anatomical model provides patient benefit, whereas a VCR or CD player does not). Items should be offered only occasionally, even if each individual item is appropriate.</p>	<p>✓ No items intended for the personal benefit of HCPs (such as floral arrangements, artwork, music CDs or tickets to a sporting event).</p> <p>✓ No payments in cash or cash equivalents (such as gift certificates), except as compensation for bona fide consulting or speaking services.</p> <p>✓ Appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.</p> <p>✓ No golf balls or sports bags.</p> <p>✓ No items such as gasoline intended for the personal benefit of an HCP, even if provided with product information at the same time.</p> <p>✓ <b><i>NOT appropriate to provide items for the HCP's use that do not advance disease or treatment education, even if they are practice-related items of minimal value (such as pens, notepad, mugs or other reminder items with company or product logos). These items should not be offered to HCPs or staff.</i></b></p> <p>✓ <b><i>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 his or her 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 individual item is appropriate.</i></b></p> <p>✓ <b><i>Stethoscopes are not permitted because they are not intended for patient education.</i></b></p> <p>✓ <b><i>Anatomical models, textbooks, informational sheets and brochures, patient self-assessment and tracking tools, or written materials that inform patients about adherence to medications, healthy lifestyle choices or the availability of patient assistance programs are appropriate</i></b></p>

	<b>Original PhRMA Code (2002)</b>	<b>Revised PhRMA Code (2008)</b> <i>(capped at \$100 value).</i>
<b>Charity, Charitable Donations</b>	✓ 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.	✓ Same as 2002 Code.
<b>Independence and Decision Making</b>	✓ No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to an HCP in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of an HCP's prescribing practices.	✓ Same as 2002 Code.
<b>Prescriber Data</b>		<ul style="list-style-type: none"> <li>✓ <b>Companies that choose to use non-patient identified prescriber data to facilitate communications with HCPs should use this data responsibly, which means:</b> <ul style="list-style-type: none"> <li>○ <i>respect confidential nature of prescriber data;</i></li> <li>○ <i>develop policies regarding the use of the data;</i></li> <li>○ <i>educate employees and agents about policies;</i></li> <li>○ <i>maintain an internal contact person to handle inquiries regarding the use of the data; and</i></li> <li>○ <i>identify appropriate disciplinary actions for misuse of this data;</i></li> <li>○ <i>honor requests of HCP who asks that his or her prescriber data not be made available to company sales representatives.</i></li> </ul> </li> </ul>
<b>Training and Conduct of Company Representatives</b>		<ul style="list-style-type: none"> <li>✓ <b>Provide training on applicable laws, regulations, and industry standards (including PhRMA Code) regarding interactions with HCPs to representatives employed by or acting on behalf of the Company who visit HCPs.</b></li> <li>✓ <b>Train representatives to ensure general science and product-specific information so that representatives can provide accurate, up-to-date information, consistent with FDA requirements.</b></li> <li>✓ <b>Periodically assess representatives' compliance with company policies and provide updated or additional training as needed.</b></li> </ul>
<b>Adherence to Code</b>	✓ Each member company is strongly encouraged to adopt procedures to assure adherence to the Code.	<ul style="list-style-type: none"> <li>✓ <b>All companies that interact with HCPs about pharmaceuticals should adopt procedures to assure adherence to this Code.</b></li> <li>✓ <b>Companies that publicly announce their commitment to abide by the Code and who complete an annual certification (signed by the CEO or Chief Compliance Officer) stating that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site.</b></li> <li>✓ <b>Public website will also identify the companies who commit to abide by the Code and provide contact information for their Chief Compliance Officers.</b></li> </ul>

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		<ul style="list-style-type: none"> <li>✓ <i>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.</i></li>   <li>✓ <i>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.)</i></li> </ul>