

KING & SPALDING LLP

The New PhRMA Code: Changes and Analysis

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The New Code: Major Changes

- **Gifts to healthcare professionals (“HCPs”):**
 - No out-of-office meals by sales reps (or immediate managers)
 - Reminder items such as pens, note pads, mugs, etc., are not allowed; only items designed primarily for the education of patients or HCPs
 - Entertainment or recreational items are not allowed
- **Consultants and Speakers:**
 - Selection criteria provided
 - Compensation should be reasonable, based on fair market value (“FMV”)
 - No recreational/entertainment events; no resorts for meetings
 - Annual per-physician cap on compensation for speaking activities
 - Periodic monitoring of speaker programs for compliance
 - Policies to address the appropriate use of speakers, including utilization of speakers after training, appropriate number of engagements
- **Funding of CME:**
 - Follow ACCME standards
 - Meals cannot be directly provided

The New Code: Major Changes

- **Training of sales representatives**
 - Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply
- **Responsible use of prescriber data**
 - Companies that choose to use non-patient identified prescriber data to facilitate communications with HCPs should:
 - (a) respect the confidential nature of prescriber data;
 - (b) develop policies regarding such data;
 - (c) educate employees and agents about those policies;
 - (d) maintain an internal contact person to handle inquiries; and
 - (e) identify appropriate disciplinary actions for misuse of this data
 - Companies should abide by the wishes of any HCP who asks that his/her prescriber data not be made available to company sales reps; encourages companies to follow rules of voluntary programs that facilitate prescribers' ability to make this choice

The New Code: Major Changes

- **Companies should require HCP-consultants who are members of formulary or clinical practice guideline committees to disclose their manufacturer ties**
 - Does not describe to what extent manufacturers should check to ensure disclosures occur
- **Compliance with the Code:**
 - Companies may choose to make annual certification by Chief Executive Officer and Chief Compliance Officer that company has policies and procedures in place to foster compliance with the Code
 - Periodic external review of the company's compliance with the Code (at least every three years)

Revised Code: New, Modified, Substantially Similar

Topic	Section of Revised Code	Section of 2002 Code	New	Modified	Similar
Basis of Interactions	1	1	✓*		
Informational Presentations and Accompanying Meals	2	2		✓	
Prohibition on Entertainment and Recreation	3	N/A	✓		
Support for Continuing Medical Education	4	3		✓	
Support for Third-Party Educational and Professional Meetings	5	3		✓	
Consultants	6	4		✓	
Speaker Programs and Speaker Training Meetings	7	5	✓*		
HCPs who are Members of Formulary Committees or Committees that Develop Clinical Practice Guidelines	8	N/A	✓		
Scholarships and Educational Funds	9	6			✓
Prohibition of Non-Educational and Practice-Related Items	10	7		✓	
Educational Items	11	7		✓	
Use of Prescriber Data	12	N/A	✓		
Independence and Decision Making	13	8			✓
Training and Conduct of Company Representatives	14	N/A	✓		
Adherence to the Code	15	9	✓*		

* Although the 2002 Code addresses this issue, the Revised Code contains a significant amount of new information

Revised Code: Modified Sections

Note: Only provisions that are new or vary from the 2002 Code are highlighted. It is important to note that several provisions in the following modified sections are very similar (if not identical) to the 2002 Code; those similar provisions are not highlighted.

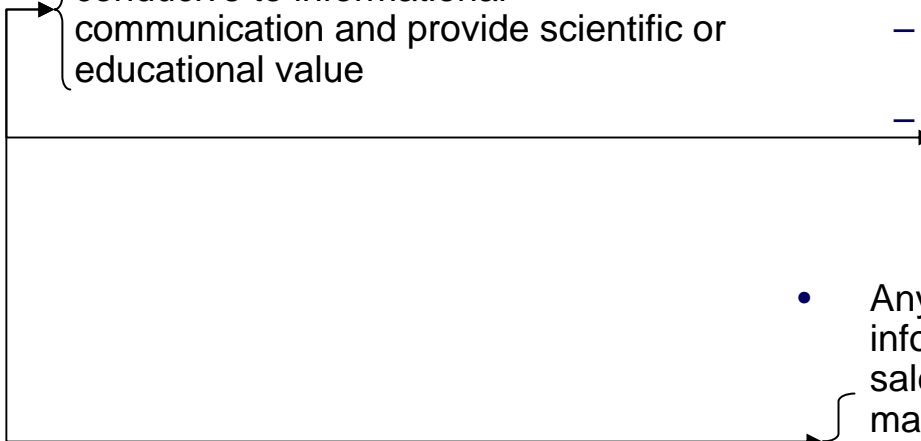
Informational Presentations and Accompanying Meals

July 2002 Code (Section 2)

- In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered so long as they:
 - (a) are modest as judged by local standards; and
 - (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value

Revised Code (Section 2)

- It is appropriate for occasional meals to be offered as a business courtesy to HCPs as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals:
 - (a) are modest as judged by local standards;
 - (b) are not part of an entertainment or recreational event; and
 - (c) are provided in a manner conducive to informational communication. (new/variation)
- Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings (new/variation)



Company Support for CME

Note: Company support for non-accredited third-party educational or professional meetings remains unchanged under the Revised Code (Section 5)

July 2002 Code (Section 3)

- Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines.

Revised Code (Sections 4)

- A company should separate its CME grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment. (new)
- Should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit the CME. (new)
- The company should not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company. (new)
- A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants. (variation)

Consultants

July 2002 Code (Section 4)

- Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. (removed)

- Any social or entertainment events during consultant meetings are clearly subordinate in terms of time and emphasis.

Revised Code (Section 6)

- Consultants should be selected based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. (new)
- Companies should ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or treatment. (new)
- Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on FMV. (new)
- Resorts are not appropriate venues for consultant meetings. (new/variation)
- While modest meals or receptions may be appropriate during company-sponsored meetings with healthcare professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings. (variation)

Gifts - Educational and Practice-Related Items

July 2002 Code (Section 7)

- Items primarily for the benefit of patients may be offered to HCPs if they are not of substantial value (\$100 or less).
- Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar "reminder" items with company or product logos).

Revised Code (Sections 10 & 11)

- Where permitted by law, companies may 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 have value to HCPs outside of their professional responsibilities.
(new/variation)
- Providing items for healthcare professionals' use that do not advance disease or treatment education — even if they are practice-related items of minimal value (such as pens, note pads, mugs, clip boards, and similar "reminder" items with or without company or product logos) — may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to HCPs or members of their staff, even if they are accompanied by patient or physician educational materials. *(variation)*

The New Code: Themes

- New limits
 - Ban on out-of-office meals by sales personnel
 - Ban on entertainment and recreation
 - Far more strict limits on gifts
- More rigorous internal standards and processes
 - Criteria for speaker selection
 - Criteria for educational funding
- New topics
 - Promotional guidelines
 - Formulary committee disclosure
 - Prescriber data
- Monitoring and assessment
 - Speaker programs
 - Field sales activities
 - External review of compliance
- Enhanced compliance provisions

Questions?