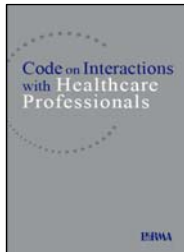


## Newaygo ViewPoint: The Revised PhRMA Code



**News Item:** On July 10<sup>th</sup> 2008, the PhRMA released a revised “*Code on Interactions with Healthcare Professionals.*” This revised code is a follow-up to the PhRMA guidelines that were last issued in 2002 and will be effective January 1, 2009 (however, on a voluntary basis.) The code applies to pharmaceutical companies who are members of PhRMA, but does not apply to biotechnology companies or medical device companies.

### *Newaygo ViewPoint*

Since the release of the revised PhRMA code on Interactions with Healthcare Professionals, there has been considerable discussion in the press and on the internet industry blogs regarding these revisions and the implications for companies and their policies and procedures for interacting with healthcare professionals.

The revisions are an extension of the 2002 PhRMA code which laid the foundation for the many healthcare law compliance changes seen in the industry over the past six years. Over time, Pharmaceutical companies have been updating their policies and procedures regarding interactions with healthcare professionals and the latest PhRMA code revisions add even more specificity, depth, and additional limitations on how the industry should engage healthcare professionals.

*The implications of the latest revisions are clear;* interacting with healthcare professionals will become even more complex, the cost to manage, monitor and report on these interactions will increase, and there is even greater potential for confusion and error amongst those who interact with healthcare professionals.

The Newaygo PharmaGroup team has reviewed the revised PhRMA code and developed the following *Newaygo ViewPoint*. This document provides a top-line summary of changes as well as a strategic evaluation of the key changes we feel are either (1) a significant departure from the past or (2) changes that may have the greatest impact on how you interact with healthcare professionals. We have also provided recommendations on how to implement the revised PhRMA code.

We hope this *ViewPoint* provides some clarity and an experienced perspective on the new PhRMA code.

Please contact us if you have any questions on this *ViewPoint* or would like to discuss how we may be able to help you implement the revised PhRMA code.

The Newaygo PharmaGroup Team

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## *Overview of the Revised PhRMA Code Changes*

### **Are The Changes Really ‘Voluntary’?**

Since the release of the revised code, there have been questions regarding the ‘voluntary’ nature of the guidelines. The PhRMA code is listed as voluntary, meaning a PhRMA member may choose not to implement all or parts of the code. However, we feel these changes are an effort by PhRMA to establish a more favorable public profile and avoid further restrictive legislation and believe the vast majority of PhRMA members will abide by the guidelines. One consideration is that the ‘voluntary nature’ of the revised code may provide flexibility in terms of “when” the changes will be implemented so the pace of change is likely to vary from company to company.

### **Section by Section Overview of Changes**

Section	Changes	Potential Impact of Changes*
2. Informational Presentations by Company Reps and Accompanying Meals	Meals only to be provided at in-office or in-hospital settings (e.g. restaurant meals and no dine-and-dash meals.)	Low
3. Prohibition on Entertainment and Recreation	No entertainment or recreation whatsoever, including speaker programs and consultant meetings.	Low
4. Pharmaceutical Company Support for CME	Separate its CME grant-making functions from its sales and marketing departments.	<b>High</b>
	Develop objective criteria for making CME grant decision.	Low
	Follow standards for commercial support established by the ACCME or other entity that may accredit the CME.	Low
	No input or involvement in CME content even if the company’s input is requested from the CME provider.	Low
5. Pharmaceutical Company Support for Third-Party Educational or Professional Meetings	Companies can no longer provide meals at CME events (although the CME provider can decide to provide a meal)	Low
	Definitions of third-part educational or professional meetings are now provided.	Low
	Financial support should not be given to attendees of these meetings	Low
	3 <sup>rd</sup> party organizes should have control of content and finances	<b>Moderate</b>
6. Consultants	Modest” meals can provided at these meetings	Low
	No recreation or entertainment permitted	Low
	No resort locations for meetings	Low
	Modest” meals can be provided	Low
	Consultant fees should be based on fair market value	<b>High</b>
	Selection of consultants should be based on defined criteria	Low
	Interaction should not be an inducement for prescribing	Low

7. Speaker Programs and Speaker Training Meetings	Same as above for consulting	Low
	Cap total annual compensation paid to an individual HCP in connection with all speaking arrangements and develop policies on the use of speakers, including appropriate number of engagements for any one speaker over time.	<b>High</b>
	Monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.	<b>High</b>
8. Healthcare Professionals Who Are Members of Committees That Set Formularies or Develop Clinical Practice Guidelines	Speakers and consultants should disclose to the formulary or guidelines committees the existence and nature of the relationships with the company. This disclosure should extend at least two years beyond the termination of the speaker or consulting arrangement.	<b>Moderate</b>
9. Scholarships and Educational Funds	Financial assistance may be offered but the selection of individuals who will receive the funds should be made by the academic or training institution.	Low
10. Prohibition of Non-Educational and Practice-Related Items	No distribution of non-educational items such as pens, note pads, mugs and other reminder items	Low
11. Educational Items	Educational items designed to education patients or healthcare professionals can be offered but must be less than \$100 and should only be offered on an occasional basis.	Low
12. Prescriber Data	Companies should use prescriber level data responsibly.	Low
	Companies should abide by requests of physicians who do not want their prescriber data given to sales representatives.	<b>High</b>
13. Independence and Decision Making	No changes from 2002 code	N/A
14. Training and Conduct of Company Representatives	All company representatives who interact with healthcare professionals should receive training on applicable laws, regulations and industry codes including PhRMA code that govern the representatives' interactions with healthcare professionals.	<b>Moderate</b>
	Companies should assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct.	<b>High</b>
	Companies should take appropriate action when representatives fail to comply.	<b>High</b>
15. Adherence to Code	All companies should adopt procedures to assure adherence to this Code.	<b>High</b>
	Companies should publicly announce their commitment to abide by the Code	Low
	Companies should 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	Low
	Public website will also identify the companies who commit to abide by the Code and provide contact information for their Chief Compliance Officers.	Low

\* Newaygo assessment on the degree of change and potential impact on business and business operations based on our assessment on where the majority of companies are currently at in terms of healthcare law compliance management.

## ***Priority Requirements***

Outlined below is the Newaygo assessment on which of the changes in the revised PhRMA code may have the biggest impact for pharmaceutical companies, the implications and several recommendations to meet the guideline requirements.

<b>1. Speaker Caps and Utilization</b>		
Description of the Revised Code	<ul style="list-style-type: none"> <li>• “Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements.”</li> <li>• “Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.”</li> </ul>	
Change from the Past	5 out of 5 (1=low, 5=high)	Most companies may not have implemented speaker caps or have policies regarding the number of engagements for any particular speaker over time.
Impact on Business & Operations	5 out of 5 (1=low, 5=high)	High impact on business policy, systems and resources.
Implications	<ul style="list-style-type: none"> <li>• Companies will need to establish a policy and technical system to monitor speaker caps and utilization.</li> <li>• This system should also consider a process to gather information and manage cap and utilization for when US-based HCP’s are used as paid speakers outside of the US.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>• Update/create Speaker Program SOP.</li> <li>• Update/create speaker database and management system with effective system and process controls for utilization (including ex-US utilization if this is considered in-scope for your organization.)</li> <li>• Prepare and re-train company members involved in speaker program on enhancements and changes.</li> <li>• Appropriately communicate speaker utilization changes to speakers.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>• Implemented corporate-wide changes to speaker program policy, procedures and systems, including ex-US utilization and speaker training policy.</li> <li>• Designed technical systems and control procedures for speaker utilization.</li> <li>• Trained 1,000+ colleagues on speaker program changes.</li> <li>• Developed and communicated with speakers on company speaker policy changes.</li> </ul>	

***Priority Requirements (continued)***

<b>2. Speaker Program Monitoring</b>		
Description of the Revised Code	<ul style="list-style-type: none"> <li>• “Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.”</li> </ul>	
Change from the Past	5 out of 5 (1=low, 5=high)	Few companies regularly monitor or audit speaker programs for compliance.
Impact on Business & Operations	5 out of 5 (1=low, 5=high)	High impact on business policy, systems and resources
Implications	<ul style="list-style-type: none"> <li>• Companies will need a speaker program monitoring SOP, including a violation and escalation process for local speaker programs.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>• Create a monitoring and auditing plan and establish resourcing.</li> <li>• Update/create Speaker Program SOP to include monitoring.</li> <li>• Update/create violation policies and procedures for findings that come from monitoring.</li> <li>• Communicate with company members regarding the monitoring and violation policies and procedures.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>• Developed corporate-wide speaker program auditing and monitoring to regularly evaluate local speaker programs for FDA requirements.</li> <li>• Developed corporate-wide violation and escalation policies and procedures.</li> </ul>	

***Priority Requirements (continued)***

<b>3. Use of Prescriber-level data</b>		
Description of the Revised Code	<ul style="list-style-type: none"> <li>• “Companies that choose to use non-patient identified prescriber data to facilitate communications with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.”</li> <li>• “In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives.”</li> </ul>	
Change from the Past	5 out of 5 (1=low, 5=high)	Few companies have a policy for use of prescriber level data or a system for physicians to “opt-out”
Impact on Business & Operations	5 out of 5 (1=low, 5=high)	High impact on business systems and resources, as well as HCP relations if opt-outs not appropriately managed.
Implications	<ul style="list-style-type: none"> <li>• Companies will need to establish policies and procedures and a company-wide system for managing individual prescriber-level data including an “opt-out” function and monitoring/violation/escalation process. This could be an extensive change.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>• Update/create an SOP regarding use of prescriber-level data.</li> <li>• Create a technical system or process to control the use of prescriber-level data for physicians who request not to have their prescribing data made available.</li> <li>• Communicate and train company members on SOP regarding use of prescriber-level data.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>• Hands-on sales and marketing experience with prescriber-level data and how it is utilized.</li> <li>• Developed complex change management plans for multiple changes over a planned period of time.</li> </ul>	

***Priority Requirements (continued)***

<b>4. Entertainment and Recreation</b>		
Description of the Revised Code	<ul style="list-style-type: none"> <li>• “To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company.”</li> </ul>	
Change from the Past	3 out of 5 (1=low, 5=high)	In the past, the code permitted entertainment and recreation at advisory boards, consulting meetings, and speaker training. Going forward, no entertainment or recreation is permitted.
Impact on Business & Operations	3 out of 5 (1=low, 5=high)	Moderate impact on business operations; training and monitoring of activities. Companies retain the ability to interact with healthcare professionals in a variety of setting without the use of entertainment or recreation.
Implications	<ul style="list-style-type: none"> <li>• Companies will need to update SOP’s for entertainment and recreation, and communication/train company personnel on changes.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>• Create/update SOP’s that relate to interacting with healthcare professionals.</li> <li>• Establish violation and escalation SOP that include use of entertainment and recreation.</li> <li>• Communicate and re-train company members as well as third party vendors to ensure awareness and compliance with changes.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>• Extensive experience in writing and updating SOP’s for a wide variety of commercial activities involving healthcare professional interactions.</li> <li>• Developed communications and trained for 1,000+ colleagues on a variety of commercial practice SOPS.</li> <li>• Developed communications and training for 3<sup>rd</sup> party vendors.</li> </ul>	

***Priority Requirements (continued)***

<b>5. Continued Medical Education (CME)</b>		
Description of the Revised Code	<ul style="list-style-type: none"> <li>“A company should separate its CME grant-making functions from its sales and marketing departments.”</li> </ul>	
Change from the Past	3 out of 5 (1=low, 5=high)	In the past, CME grants were largely the responsibility of marketing. Currently, we believe most companies have started to move CME grant functions out of Sales and Marketing department.
Impact on Business & Operations	3 out of 5 (1=low, 5=high)	Low to moderate impact; CME grants can still be provided but with no input or involvement of the company.
Implications	<ul style="list-style-type: none"> <li>Companies will need to update CME Grant SOP's and grant management systems, and implement training to update the organization on changes. The CME grant SOP and system should include how to manage regional requests.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>Establish a CME grant process and system that is independent of Sales and Marketing.</li> <li>Update/create SOP for CME Grants.</li> <li>Update CME grant process or system to ensure a high level of efficiency, effectiveness and compliance.</li> <li>Communicate to and train company members on CME grant changes and requirements.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>Extensive experience in writing and updating grant SOP's, including CME grants and Independent Research Grants.</li> <li>Experience in establish effective grant submission and review systems.</li> <li>Compliance training of 1,000+ colleagues.</li> </ul>	

<b>6. Gifts to Healthcare Professionals</b>		
Description of the Revised Code	<ul style="list-style-type: none"> <li>• “Non-educational items (such as pens, note pads, mugs and similar “reminder” items that have company or product logos) should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.”</li> </ul>	
Change from the Past	5 out of 5 (1=low, 5=high)	In the past, all companies have provided company or brand reminder items.
Impact on Business & Operations	2 out of 5 (1=low, 5=high)	Low to moderate impact; potential advertising reminder is lost (but to consider, ROI on such items has never been clearly established) but resources are saved for other promotional activities.
Implications	<ul style="list-style-type: none"> <li>• Companies will need to eliminate the distribution of all non-educational items, including those provided at speaker training and consultant meetings, and ensure members are adequately trained</li> <li>• Opportunity to re-direct promotional resources spent on non-educational items to other promotional and education opportunities.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>• Incorporate the change regarding distribution of non-educational items into all SOP relating to interactions with healthcare professionals</li> <li>• Establish a change management plan and timelines for the discontinuation of non-educational items.</li> <li>• Establish ‘talking points’ and Q&amp;A documents to assist company representatives with questions from physicians.</li> <li>• Consider establishing a brand plan to re-direct non-educational item resources into other promotional and educational activities.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>• Extensive experience in change management plans</li> <li>• Experience in developing communication tools such as ‘talking points’, Q&amp;A and FAQ documents, and one-page “how-to” job-aids.</li> <li>• Experience in managing brands in an environment (Canada) where non-educational items are not permitted.</li> <li>• Extensive experience in brand promotional and educational programs.</li> </ul>	

7. Company Representatives and Meals		
Description of the Revised Code	<ul style="list-style-type: none"> <li>“In connection with such presentations or discussions [by sales representatives], it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals 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.”</li> <li>“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.”</li> </ul>	
Change from the Past	5 out of 5 (1=low, 5=high)	<p>FF not providing meals is a significant departure from the 2002 code.</p> <p>‘Modest’ meals are still permitted at speaker training and speaker dinner programs.</p> <p>‘Modest’ meals are permitted in conjunction with non-Sales company representatives.</p>
Impact on Business & Operations	2 out of 5 (1=low, 5=high)	Low to moderate impact; We believe the number of activities involving sales representative providing non-office related meals with HCP were relatively low.
Implications	<ul style="list-style-type: none"> <li>Companies will need to update their SOP’s regarding provision of meals and train company representatives on the new SOP.</li> <li>Additionally, monitoring and auditing systems as well as violation and escalation SOP will need to be established and implemented.</li> </ul>	
Newaygo Recommendations	<ul style="list-style-type: none"> <li>Incorporate the changes regarding the provision of meals into all SOP’s relating to interactions with healthcare professionals.</li> <li>Update/create a violation and escalation process.</li> <li>Communicate and train company members on the changes.</li> </ul>	
Our Experience in this Area	<ul style="list-style-type: none"> <li>Extensive experience in writing and updating SOP.</li> </ul>	

## ***What Should be Done Next?***

*"If you're going to panic, panic constructively."*

Panic is not something we recommend, however, the depth and breadth of changes recommended by the revised PhRMA code may seem daunting. For all organizations, we recommend the following:

1. Conduct a **thorough analysis and diagnosis** of revised PhRMA code requirements compared to your company policies and procedures to determine gaps and needs. This analysis should include:
  - a. Review of existing policies and procedures
  - b. Review of centralized systems and technology
  - c. Review of compliance infrastructure and resourcing
  - d. Review of company compliance framework
2. Establish a **plan-of-action** to close the gaps that includes:
  - a. Prioritization of changes and enhancements
  - b. Resource requirements clearly outlined and secured
  - c. Leadership buy-in and stakeholder mapping and teams to assist with change
  - d. Change management and training plan and timeline.
3. Establish a company-wide **compliance framework** that applies to all commercial practices relating to interactions with healthcare professionals. The Newaygo compliance framework includes:
  - a. Governance/Accountability System and Performance Goals
  - b. Policies
  - c. Written Standards
  - d. Education
  - e. Monitoring and Escalation

## ***How We Can Help***

At Newaygo, we have extensive commercial experience and have implemented corporate-wide compliance and other business operational changes. We have managed requirements relating to corporate integrity agreements and we know the complexities that are inherent in the revised PhRMA code.

We can help you navigate the revised PhRMA code and determine potential gaps, assist with the development of an effective, efficient and compliant plan of action that uses the highest standards, and implement the changes using a series of effective and impactful tools and techniques so that your organization quickly and effectively harmonizes with the PhRMA code. As an example, we have a FMV methodology that has been industry-implemented and a software tool called *HCP Contractor™* that manages HCP profiles and the contracting process for all fee-for-service activities involving a HCP.

In summary, we can eliminate the complexity of the revised PhRMA code, quickly, effectively and affordably.

Please contact us for more information on how we can add value to your PhRMA code plan-of-action. We look forward to the opportunity of working with you.