



July 11, 2008

Analysis

Reducing the Impact of Pharmaceutical Marketing to Physicians and Promoting Appropriate Prescribing and Drug Safety

The pharmaceutical industry spends nearly \$30 billion annually on marketing. The majority (including samples) is spent on direct marketing to physicians (Donohue, NEJM, 2007).

Nationwide, prescription drug spending rose to \$234.1 billion in 2008, almost six times the \$40.3 billion spent in 1990 (Kaiser Family Foundation, 2010).

This fact sheet was created in collaboration with



Old vs. New: The PhRMA Marketing Code 'Interactions with Healthcare Professionals'

Introduction

On July 10, 2008, the Pharmaceutical Researchers and Manufacturers of America issued a revised voluntary Code on "Interactions with Healthcare Professionals." The following is a brief summary and comparison of the previous Code, revised in 2002, and the latest one.

PROVISION	ANALYSIS
Section 2 – Meals	
Meals in-office or in-hospital with rep only. Must be modest by local standards. No spouses. No takeaway.	<p>No major change to existing code for in-office meals.</p> <p>Eliminates lunch with a drug rep at a restaurant, but still allows for other industry personnel to provide "modest" restaurant meals.</p> <p>Also allows for modest meals at a restaurant if a group of physicians gather to hear an industry-funded physician speaker.</p> <p>Allows companies to sponsor meals at third-party conferences and meetings (including those at which CME is provided as part of the program).</p>
Section 3 - Entertainment	
No entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, whether or not there is an educational component.	No major change to the status quo, although it does close a loophole that allowed for entertainment of consultants and speakers.

Section 4 - CME	
Companies to separate CME grant-making functions from sales and marketing departments.	Consistent with OIG recommendations.
No direct subsidy to attendees for travel or attendance.	Likely little effect.
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.	Consistent with new ACCME standards. Concern is that CME companies know how to produce the content that companies want and will do so because they depend on ongoing funding.
No direct meals.	Because CME providers can be funded to provide meals, this will have little material effect. In addition, meals may be provided at third-party conferences and meetings at which CME is provided as part of the program.
Section 5 – Meetings support	
No direct support of individual attendees	A welcome change.
Support for meeting ok.	Status quo
Company should not influence content	Companies will still choose to fund meetings consistent with their goals
No support, direct or indirect, of reimbursement for attendees or travel for spouses.	Status quo
Section 6 – Consultants	
Companies should continue to ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.	Status quo
Compensation must be reasonable and fair market value.	Still allows for lucrative relationships
No token or advisory relationships for time or travel.	A welcome recognition of the problem, but lack of oversight means hard to assess this. If it is a meaningful change, we would expect to see decrease in \$ value of consultancies in VT and other state data. Meanwhile, effectiveness of this is subject to the effectiveness of the provisions below.
Bonafide relationships defined by some of the following:	
Written contract specifies services and payment	
A legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering into arrangements	This is important if it were truly implemented

The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;	This is important if it were truly implemented
Retaining company maintains records concerning and makes appropriate use of the services provided by consultants;	
Venue is conducive to the consulting services and activities related to the services are the primary focus; specifically, resorts are not appropriate venues.	No major change to current practice, although the explicit exclusion of resort venues is welcome.
Modest meals	
No spouses.	
Section 7 – Speakers	
Speakers must be trained on the product and on FDA rules	Status quo
Reasonable compensation allowed, including travel and honoraria	Status quo, except that resorts are no longer allowed as a training venue.
Annual cap on individual speaker fees to be established by each company	Any effect will depend at what level individual companies set the cap.
Section 8 – Formularies and Treatment Guidelines	
Industry consultants who also serve on formulary or practice guidelines committees must disclose industry relationships to the committee	An improvement, although it would be better if such relationships were also disclosed publicly.
Disclosure requirement to extent two years after end of financial relationship with industry	
Section 9 – Scholarships and education	
Recipients to be chosen by the institution, not industry	A welcome change.
Section 10 – Non-educational items	
No non-educational items, including pens, pads, mugs, reminder items with product logos	A welcome change.
Stethoscopes, etc. not allowed.	A welcome change.
Section 11 – Educational items	
Educational items for clinicians or patients allowed if under \$100	Would limit expensive textbooks. Would still allow for a premium subscription to a marketing-supported drug information system (eg Epocrates).
Items should not have value outside intended use (eg CD player not allowed)	Would limit some potential for abuse.
Items to be offered only occasionally	Vague; no audit. Public reporting would enhance these provisions.
Section 12 – Prescriber data	
Respect voluntary opt-out programs	Status quo

Otherwise, continue as current practice	
Section 15 – Adherence to code	
Website will list companies that pledge to adhere to Code	We need to list companies that have not pledged compliance and companies that are not PhRMA members. And device makers.
Companies encouraged to seek external verification every 3 years that appropriate policies for Code adherence are in place	Good, but how to assess practice versus policies? Mandatory reporting would help.