



New Medicines. New Hope.



Updates to the PhRMA Code on Interactions with Healthcare Professionals

Diane E. Bieri
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Long-standing Commitment to Ethical Interactions with Healthcare Professionals



- Exchange of information between pharmaceutical companies and physicians is essential to providing optimal patient care
- Interactions benefit patient care through the exchange of information about new medicines, new uses of medicines, the latest clinical data, appropriate dosing and emerging safety issues
- PhRMA adopted the “Code on Interactions with Healthcare Professionals” to govern the pharmaceutical industry’s relationships with healthcare professionals in 2002

Biopharmaceutical Company Marketing – The Evolving Landscape



- **Patchwork of state legislation**
 - ❖ Bills proposing bans on gifts and meals to physicians; requiring reporting of various types of marketing expenses; requiring registration of company sales representatives
- **Federal legislative proposals demanding greater transparency**
 - ❖ Grassley-Kohl bill would require disclosure on HHS website of money or other things of value (e.g., meals, gifts, honoraria, consulting fees) provided to individual doctors in connection with marketing activities
- **Academic medical centers, others in physician community addressing perceived conflicts of interest**
- **PhRMA Code, while cited by OIG and others, is not universally known**

New PhRMA Code Demonstrates Enhanced Commitment to Responsible, Professional Interactions



- Approved unanimously by the PhRMA Board of Directors
- Code reaffirms that interactions between company representatives and healthcare professionals should be focused on informing healthcare professionals about the benefits and risks of medicines, providing scientific and educational information, and supporting medical research and education
- 30+ PhRMA members and non-member companies have signed on to revised Code (takes effect January 2009)

Structure of the Code



- Preamble: Sets out Code's core principles
- Body of Code
 - 15 sections
 - Titled for ease of reference, e.g., Informational Presentations, Consultants, CME, Use of Prescriber Data, etc.
- Question & Answer Section
 - Clarifies PhRMA's position on common questions
 - Provides PhRMA's only "interpretation" of the Code

No “Gifts” to Health Care Professionals



- Revised Code eliminates all “gifts” to physicians, including “reminder” items
- Items to educate health care professionals or their patients are appropriate (e.g., anatomical models, medical or scientific texts)
- Same rules apply to interactions with physicians in offices or at medical conferences

Company Sales Representatives' Interactions with Health Care Professionals



- Revised Code prohibits field sales representatives from providing restaurant meals to health care professionals
 - Sales representatives may provide occasional, modest meals only in physician office or hospital settings in conjunction with educational presentations
 - As in 2002 Code, “dine and dash” meals in offices still prohibited
- New provisions on training and assessment of sales representatives

Consultants and Speakers



- Spells out compensation should be reasonable and based on fair market value.
- Decisions regarding the selection or retention of consultants or speakers should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area.
- Meetings should not be held at resorts and should not include entertainment, even if incidental to business purpose of meeting.

Speakers – New Provisions



- **Utilization:** Company should develop policies addressing the appropriate use of speakers, including appropriate utilization after training and appropriate number of engagements for any particular speaker over time.
- **Monitoring:** Company should periodically monitor speaker programs for compliance with FDA regulatory requirements.
- **Caps:** Each company individually and independently should establish an annual cap on the total amount it will pay to a healthcare professional in connection with speaking arrangements.
- **Transparency about speaker programs v. CME**
 - Company and speakers should be clear about the distinction between promotional speaker program and independent medical education.
 - Speakers and their materials should clearly identify the company that is sponsoring their presentation and that the speaker is presenting information that is consistent with FDA guidelines.

Other Key Features



- Enhances the independence of Continuing Medical Education funded by companies
- Sets guidelines on the use of physician prescriber data, supporting appropriate use of the data, allowing for physician opt-out, and providing a contact for physicians
- Requires disclosure of speaker and consulting relationships with industry for physicians on formulary and guidelines committees and requires each company to cap the amount of annual compensation an individual physician speaker can receive

Revisions to the Code: Greater Transparency Regarding Company Commitments



2002 Code

- 2002 Code is voluntary, with no compliance mechanism

2008 Code

- Companies should:
 1. **State their commitment to abide by the Code;**
 2. **Self-certify annually** with signatures of CEO and Chief Compliance Officer that they have policies and procedures to foster compliance; and
 3. **Authorize PhRMA to post names and contact info for company Compliance Officers**
- Companies are encouraged to obtain **periodic, external verification on their compliance policies and procedures**
- **PhRMA will post on Web site:**
 1. Names of companies that indicate commitment to abide by Code;
 2. Status of annual certification; and
 3. When company has sought and obtained external verification of compliance policies and procedures

**PhRMA
Code
compliance
mechanism**

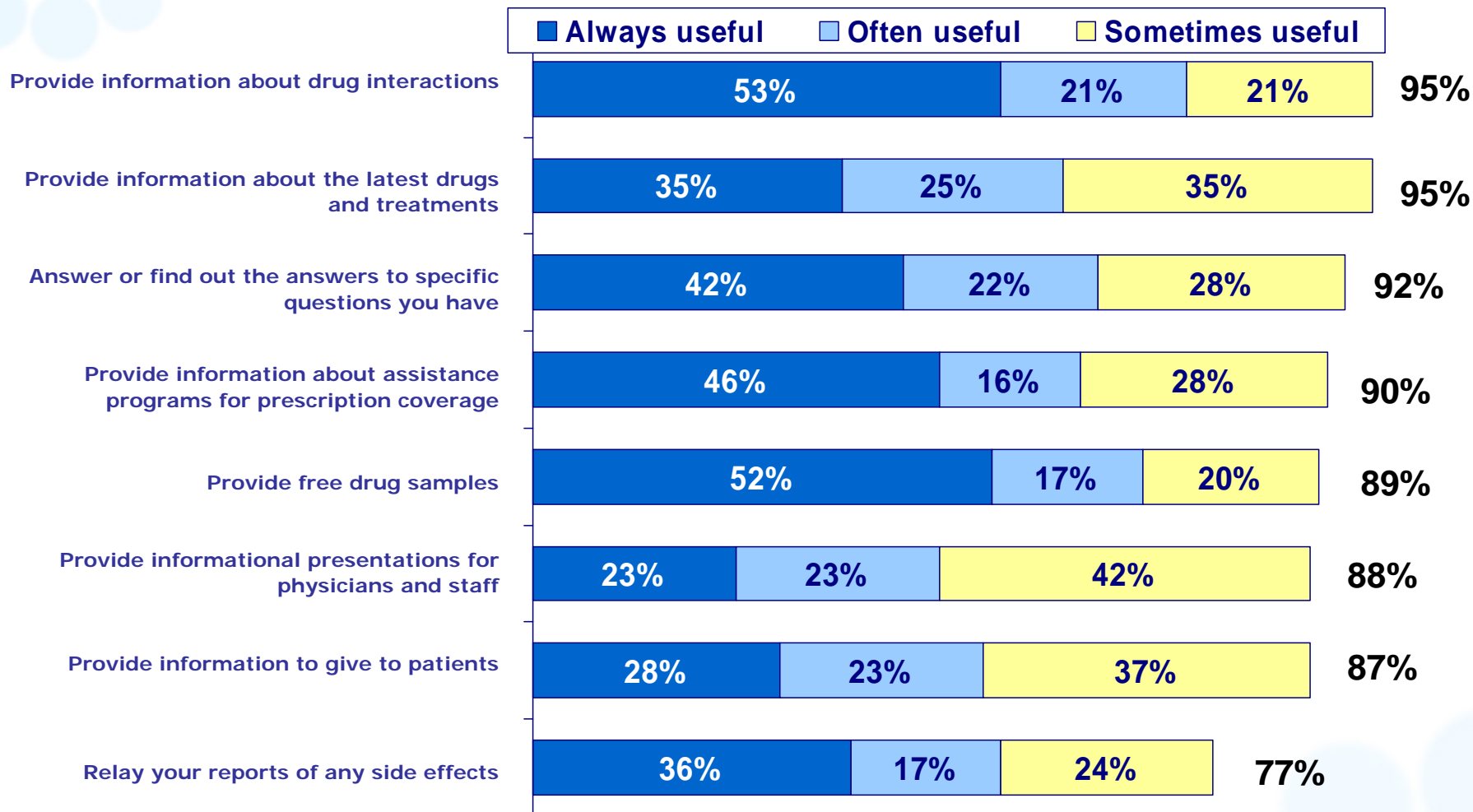
Healthcare Professionals Consider Multiple Factors in Prescribing



PhRMA



Healthcare Professionals Value the Work of Pharmaceutical Company Representatives



Source: KRC Research, Survey of Physicians about Pharmaceutical and Biotech Research Activities and Information, Commissioned by PhRMA, March 2008