

Trinkets Out, 'Educational' Gifts OK Under New Code

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The free pens and mugs adorned with the names of commonly prescribed drugs are soon to be a thing of the past, thanks to a new set of voluntary guidelines from the Pharmaceutical Research and Manufacturers of America.

But the real impact of the guidelines is still up for debate.

The voluntary guidelines, which will go into effect in January, were released this summer as pressure mounted from Congress and the academic medical community for industry to rein in its marketing practices. The new guidelines update the 2002 PhRMA Code on Interactions with Healthcare Professionals.

"Although our member companies have long been committed to responsible marketing of the life-enhancing and life-saving medicines they develop, we have heard the voices of policymakers, health care professionals, and others telling us we can do better," Billy Tauzin, PhRMA president and CEO, said in a statement.

Among the changes outlined in the new guidelines is a prohibition on even "modest" gifts to physicians if they lack educational value. For example, the ubiquitous pens and mugs given out by pharmaceutical representatives are no longer acceptable under PhRMA's new code of conduct. However, gifts valued at \$100 or less that are used primarily for patient or health care professional education, such as an anatomical model, are still allowed on an occasional basis.

The guidelines also prohibit sales representatives and their immediate managers from taking physicians out for dinner, even if they have an educational presentation to make. However, they can still provide "modest" meals, such as pizza, in the office or at the hospital if they stay to provide their educational session there. The voluntary guidelines also prohibit companies from providing any type of entertainment or recreational items such as tickets, sports equipment, or trips, even if the item is inexpensive.

In terms of continuing medical education (CME), the guidelines call on pharmaceutical companies to separate their CME grant-making functions from their sales and marketing activities. Subsidies to attend CME meetings should not be given directly to physicians, according to the guidelines. Instead, any funds should be given directly to the CME provider, who can use the money to reduce fees for all attendees. Companies are also not allowed to provide meals directly at CME events.

The guidelines continue to allow pharmaceutical companies to provide scholarships to medical students and others in training so they can attend educational conferences, as long as the recipients are chosen by the academic or training institution.

The guidelines also call for greater transparency among physicians who work as industry consultants. Physicians who serve as company consultants or speakers and also serve on committees that set formularies or clinical practice guidelines should disclose their industry relationships, according to the PhRMA guidelines.

The changes were praised by some in the medical community as progress on the part of the pharmaceutical industry to respond to criticisms and police itself.

"It's a big step forward," said Dr. David Korn, chief scientific officer for the Association of American Medical Colleges, which recently released its own report on industry funding of medical education.

The PhRMA guidelines don't go as far as some academic medical institution policies, but they are significant because they appear to have the full backing of the industry, Dr. Korn said. It shows that the pharmaceutical industry has heard the concerns of the public and has deemed some interactions to be unacceptable. "What we're talking about really is a culture change," he said.

The AAMC report calls on medical schools and teaching hospitals to prohibit any gifts from industry. The AAMC also instructs academic institutions to set up a central CME office to distribute industry funds, and strongly discourages participation by faculty in industry-sponsored speakers bureaus.

But other physicians criticized PhRMA for leaving open loopholes that allow for much of their marketing activities to continue.

The changes are primarily cosmetic, said Dr. Daniel Carlat, of the psychiatry department at Tufts University, Boston. PhRMA appears to be decreasing marketing activities, he said, but in fact they are keeping the tactics that are most successful.

The visible items like mugs, clocks, and pens don't tend to influence physicians, he said. However, the voluntary guidelines still give pharmaceutical sales representatives plenty of chances to get valuable face-time with physicians.

For example, the guidelines still allow sales representatives to provide free lunches in the physician's office or the hospital. And the code does not place any restrictions on dinners with pharmaceutical company consultants, Dr. Carlat said.

Time will tell whether the guidelines will result in any real changes, said Dr. Howard Brody, director of the Institute for the Medical Humanities at the University of Texas Medical Branch in Galveston.

Ultimately, it's up to the medical profession to make these changes, he said. Every single drug sale representative in the country would be looking for a new job if physicians refused to see them, Dr. Brody said. All physicians should start thinking about how to get educated about new treatments without meeting with sales representatives, he said. ■

POLICY & PRACTICE

Media Influences Tobacco Use

Media communications—including movies, advertising, and news—play a key role in shaping tobacco use, according to a lengthy report from the National Cancer Institute. The report noted that cigarettes are among the most heavily marketed products in the United States, and that most of the cigarette industry's marketing budget is allocated to promotional activities, especially for price discounts, which accounted for 75% of the industry's \$10 billion in total marketing expenditures in 2005. Depictions of cigarette smoking are pervasive in movies, occurring in three-quarters or more of contemporary box office hits, the NCI report said, adding that the weight of evidence indicates a causal relationship between exposure to depictions of smoking in movies and youth smoking initiation. The NCI report provides the government's strongest conclusion to date on the media's powerful and causal effect on tobacco use. Dr. Cheryl Heaton, president and CEO of the American Legacy Foundation, said in a statement. "This report provides the ammunition to tobacco control advocates around the world who are fighting to keep movies smoke free," Dr. Heaton said.

Tobacco Control Support Drops

Budgets for tobacco control programs in most states are either staying level or declining, despite increases in payments from the 1997 Tobacco Master Settlement Agreement, designed to compensate states for some of the cost of smoking-related illnesses, the American Lung Association reported. The ALA report blamed the stable or reduced tobacco control budgets on the poor economy in a number of states. The passage of smoke-free air laws also has slowed down in most states, the ALA found. Only two states this year—Iowa and Nebraska—have approved legislation to strengthen existing laws. And activity on cigarette tax increases in 2008 has been slower than in previous years, with only two states and the District of Columbia approving increases, the report said. New York's increase in the cigarette tax is the highest, at \$1.25 a pack, the ALA said.

Grants to Doctors in Hurricanes

The AMA Foundation's Health Care Recovery Fund will provide grants of up to \$2,500 to physicians in places declared disaster areas by the Federal Emergency Management Agency, and the foundation is accepting donations to help physicians who have been directly affected by Hurricane Gustav, which hit Louisiana, Mississippi, and Texas. The foundation provides the grants to physicians in FEMA-declared disaster areas to help them rebuild or restore their damaged medical practices in those locations, according to the AMA.

'Free' Rx Samples Expensive

Free drug samples provided to physicians by pharmaceutical companies actually could cost uninsured patients

more in the long run, because those patients are prescribed brand-name drugs rather than generics, according to a study done by researchers at Wake Forest University Baptist Medical Center, Winston-Salem, N.C. Physicians were three times more likely to prescribe generic medications to uninsured patients after drug samples were removed from their offices, according to the study, which looked at a large, university-affiliated internal medicine practice. After the clinic closed its drug sample closet, the percentage of prescribed generic medications rose from 12% to 40%, the researchers found. "It's true that samples can save patients money in the short run, but our study shows that they may end up paying more in the long run when they are given prescriptions for brand-name-only drugs," Dr. David Miller, an internist and the study's lead researcher, said in a statement.

Tools' Usefulness Limited

Although health plans are developing tools to help consumers compare price and quality information across hospitals and physicians, the tools' pervasiveness and usefulness are limited, according to a study by the Center for Studying Health System Change. The information provided as part of the tools often lacks specificity about individual providers, and its availability often is limited to enrollees in specific geographic areas, the study showed. When providing quality information, health plans generally rely on third-party sources to package publicly available information instead of using information from their own claims, the study found. "None of the health plans we interviewed believed that price and quality information is being used extensively by their enrollees today, in part because few have incentives in their benefit structures to encourage cost comparisons," Ann Tynan, HSC researcher and study coauthor, said in a statement.

Many Reach 'Doughnut Hole'

One in four Medicare Part D enrollees who filled prescriptions in 2007 reached the gap in coverage known as the "doughnut hole," and most remained in the doughnut hole for the rest of the year, according to an analysis from the Kaiser Family Foundation. The analysis suggested that about 3.4 million beneficiaries—14% of all Part D enrollees—reached the coverage gap last year and paid the full cost of their prescriptions for part of 2007. Beneficiaries taking drugs for serious chronic conditions had a substantially higher risk of a gap in coverage under their Medicare drug plan, the study found. For example, 64% of enrollees taking medications for Alzheimer's disease reached the coverage gap in 2007, as did 51% of those taking oral diabetes medications and 45% of patients on antidepressants, the study found. The analysis excluded beneficiaries who receive low-income subsidies because they do not face a gap in coverage under their Medicare drug plan.

—Jane Anderson