No Pens, No Coffee, No Food: How New Regulations Changed Professional Conferences

Lisa Kennedy Sheldon, PhD, APRN-BC, AOCNP®

The 36th Annual Oncology Nursing Society (ONS) Congress will be held April 28 through May 1, 2011, in Boston, MA. New regulations have changed how healthcare organizations and professional societies such as ONS may run conferences. Conference participants probably will notice the changes.

As most healthcare providers know, pharmaceutical companies no longer distribute brand-name pens, mugs, and notepads (Eisenberg, 2010). Now, all meals in hospital departments, medical offices, and restaurants that are donated by pharmaceutical companies and medical device manufacturers must be accompanied by an educational presentation, with continuing nursing education (CNE), by the industry representative; in fact, in some states, meals may not be provided at non-CNE events (Jutel & Menkes, 2008; Katz, Caplan, & Merz, 2003). In addition, the participation of these industries at national conferences has been tightly regulated at the federal and state levels (see Figure 1). Massachusetts, the site of the upcoming Oncology Nursing Society (ONS) Congress, is one of nine states that has passed strict legislation regarding how the pharmaceutical industry and medical device manufacturers participate in professional conferences, especially in terms of giveaways and meals (Jutel & Menkes, 2008; Katz et al., 2003).

Legal and Political Influence

What led to the changes? In the late 1990s and early 2000s, concerns regarding the financial relationships between healthcare providers and pharmaceutical and medical device manufacturers were called into question. Most likely, ethical questions arose, such as:

- How is the provider’s judgment affected by the relationships?
- Will conflict of interest arise in purchasing and/or prescribing?
- Will the relationships influence independent judgment?

Prior to the new regulations, the pharmaceutical industries often were paying healthcare providers to promote their products. Although paying providers to speak about the “on-label” uses of products approved by the U.S. Food and Drug Administration (FDA) is acceptable, paying providers to speak about “off-label” uses of a drug or product is not (Katz et al., 2003). In 1996, an employee of Pfizer, the world’s largest drug manufacturer, filed a civil suit regarding the company’s promotion of Neurontin ® (gabapentin) for uses that had not been approved by the FDA (U.S. Department of Justice, 2004). In 2003, Pfizer paid $430 million in a stunning criminal and civil settlement, the second-highest amount paid for a case of healthcare fraud (U.S. Department of Justice, 2004). In addition, Pfizer pleading guilty to two penalties for aggressively marketing the drug in off-label promotion, including ghost writing and educational programs for healthcare providers (U.S. Department of Justice, 2004).

Pfizer was not the only company under scrutiny. Because of increasing concerns, the government began tightening regulations regarding relationships between the pharmaceutical industry and healthcare providers. In 2003, the federal Office of Inspector General issued the first compliance guidelines for pharmaceutical companies (Office of Inspector General, 2003). In 2007, the U.S. Senate Committee on Finance investigated company grant-making policies and found that drug and device companies provided educational grants for continuing medical education (CME) in excess of $1 billion annually (Katz et al., 2003). Although providing educational opportunities and CNE and CME programs is
The following U.S. states have passed regulations regarding how the pharmaceutical industry participates in professional conferences.

- California
- District of Columbia
- Maine
- Massachusetts
- Minnesota
- New Hampshire
- Nevada
- Vermont
- West Virginia

![Figure 1. States Restricting Pharmaceutical Companies’ Influence](image)

necessary and an important part of educating providers, the U.S. Senate Committee on Finance was concerned about funding for travel and gifts and how it would influence professional judgment (Office of Inspector General, 2003).

**Professional Codes of Conduct**

The pharmaceutical industry and medical device manufacturers responded to the concerns by writing their own codes of conduct. The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents manufacturers of pharmaceutical agents such as chemotherapy drugs and antiemetics, put the *Code on Interactions With Healthcare Professionals* into effect in July 2002 (PhRMA, 2010). The code is based on the principle that the care given to patients by healthcare providers is dependent on the patient’s needs and the provider’s knowledge and experience. Participation in the code is voluntary; as of December 2010, 55 biopharmaceutical research companies had pledged to abide by the PhRMA codes (PhRMA, 2010).

The Advanced Medical Technology Association (AdvaMed) represents the manufacturers of medical devices such as implantable ports. The AdvaMed *Code of Ethics on Interactions With Health Care Providers* went into effect on January 1, 2004, and was revised in July 2009 to clarify appropriate and inappropriate activity between healthcare professionals and representatives of the industry (AdvaMed, 2009).

Despite the development of the new codes, the federal government continued to develop tighter oversight of the pharmaceutical industry and medical device manufacturers. Parts of the Physician Payments Sunshine Act of 2009, which was last referred to the U.S. Senate Committee on Finance, were absorbed into the Patient Protection and Affordable Care Act signed into law in March 2010. To increase transparency between the pharmaceutical industry and physicians, Title VI of the act established a national reporting and public access system on financial relationships between physicians and drug and device manufacturing companies. Manufacturers must report (a) transfers of anything worth more than $10, or (b) multiple transfers less than $10 each that total more than $100 a year (Office of Legislative Counsel, 2010). The act requires manufacturers of drugs, devices, and biologic or medical supplies that make a payment to a physician or group practice to report annually to the secretary of the U.S. Department of Health and Human Services (Office of Legislative Counsel, 2010). A publicly available database will be launched in 2013 linking physicians and their payments and gifts from industry (Office of Legislative Counsel, 2010). Nurses, nurse practitioners, and physician assistants are not explicitly listed in the act (Office of Legislative Counsel, 2010), but they may face scrutiny. The Institute of Medicine (2009) issued a report recommending changes to the system of funding CME programs and interactions between providers and industry.

Beginning with the revised PhRMA and AdvaMed codes of July 2009, the free distribution of noneducational branded items such as pens, notepads, and mugs was prohibited. Meals must be provided by a bonafide educational or scientific organization. Both codes permit commercial funding of continuing education programs if grants are provided directly to the professional organization or third-party event planner.

**Massachusetts Law**

Individual states have begun to regulate financial relationships to protect patients and lower healthcare costs. Massachusetts enacted the Pharmaceutical and Medical Device Manufacturer Conduct Act in August 2008 (Commonwealth of Massachusetts, 2008).

The purpose of the state law, although slightly different in wording from the PhRMA and AdvaMed codes, is to benefit patients, enhance the practice of medicine, and ensure the relationships between pharmaceutical and medical device manufacturers and healthcare providers do not interfere with the clinicians’ judgment (Wasserstein, Kirschenbaum, & Powell, 2008). It mandates a standard marketing code of conduct for pharmaceutical and medical device manufacturers. All meals provided by pharmaceutical and medical device manufacturers must be delivered in a hospital or healthcare office, and only for educational presentations. Manufacturers may not provide meals at other sites, such as conferences. That is a big change from years past, when, for example, meals were provided at ancillary events during ONS conferences.

In March 2009, the Massachusetts Department of Public Health issued rules of conduct for healthcare practitioners, including nurses, nurse practitioners, practical nurses, nurse midwives, and nurse mental health clinical specialists. The rules of conduct prohibit the following.

- Complimentary items such as coffee mugs, gift cards, and pens except as compensation for bonafide services
- Meals that are part of a recreational or entertainment event
- Grants, scholarships, or subsidies given in exchange for prescribing or using medicine or devices
- Branded items for noneducational practice (Commonwealth of Massachusetts, 2008)

The new rules of conduct in Massachusetts are more restrictive than the PhRMA or AdvaMed codes and are among the strictest at the state level. Practicing healthcare providers from Massachusetts will have to comply with the state’s rules of conduct when invited to or presenting at events funded by drug or device manufacturers in other states. Theoretically, the provision of coffee to Massachusetts’ healthcare providers by pharmaceutical representatives could be seen as a violation of the new rules. Although the components of meals are not specifically defined by the regulations, it is apparent
that they also include beverages such as coffee. Violators may be fined $5,000 for each occurrence, transaction, and/or event (Commonwealth of Massachusetts, 2008). Pharmaceutical and medical device manufacturers also must report any payments greater than or equal to $50, and that disclosure becomes public (Commonwealth of Massachusetts, 2008).

Effect on Oncology Nursing Society Congress

So what do the regulations mean when planning a national conference for oncology nurses in Massachusetts? The ONS Congress Planning Team has been striving to create an exciting and educational Congress for 2011. The Planning Team has been working diligently with the pharmaceutical industry and medical device manufacturers to plan educational opportunities that offer oncology nurses the information they need to provide the highest quality patient care. They also are trying to educate oncology nursing professionals about the regulation changes at the national and state levels on the ONS Web site (ONS, 2010).

If you are attending the ONS Congress in Boston, understand that changes from many levels have altered the historical setup of professional conferences in the United States. The healthcare industry has experienced these changes for a few years and has experience in delivering educational opportunities for healthcare professionals through different avenues. ONS will continue to offer high-quality educational opportunities to oncology nursing professionals to improve the care of people with cancer within the scope of the new guidelines.

Please visit the Congress exhibitors to learn more about the advances in treatment for people facing cancer. Remember to bring your own coffee and pen, and enjoy Congress 2011!

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Author Contact: Lisa Kennedy Sheldon, PhD, APRN-BC, AOCNP®, can be reached at l.kennedysheld@comcast.net, with copy to editor at CJONEditor@ons.org.

References


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