



Taking Stock of the Marketing Restrictions and Prohibitions of Academic Medical Centers

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Marketing in today's regulatory environment is challenging for sales representatives, marketing teams, compliance departments and legal counsel in the life sciences industry. As more states enact laws restricting marketing activities and requiring marketing disclosures, the difficulties, both at home and in the field, grow exponentially. In March, Congress passed legislation that will require life sciences companies to track expenditures on healthcare practitioners nationwide beginning in 2012. That legislation, however, allows states to mandate additional disclosures, as well as to limit or prohibit certain marketing activities.

While state and federal governments and agencies are crafting legislation, writing regulations, and creating reporting formats, individual medical institutions are adopting and enforcing their own policies and procedures that limit the marketing activities of the life sci-

ences industry. Although these policies do not have the weight of law or associated civil or criminal liability, they do impact the interactions between industry and medical professionals and provide their own penalties. Thus, it is critical to the success of a marketing campaign for both home office and field personnel to be aware of and compliant with these policies.

Background

States have been interjecting themselves in the marketing and promotional departments of life sciences companies for several years. Their regulations have been bold and created headlines. Individual medical facilities, conversely, have quietly been placing restrictions on industry interactions with healthcare professionals. The news media, medical publications, and federal and state prosecutions have drawn attention to the interactions between medical professionals and the life sciences industry. This

attention has led to increased scrutiny on the real and perceived conflicts of interest that are created when industry interacts with medical professionals.

In a 2006 *Journal of the American Medical Association* (JAMA) article, the authors argued that academic medical centers (AMCs) were the ideal venue for conflict of interest reform in medicine for at least two reasons: first, AMCs have a great deal of influence over the medical community; and second, AMCs train future medical professionals who will learn their practice habits early on, at an AMC.¹

In 2006, the Association of American Medical Colleges (AAMC) appointed a Task Force on Industry Funding of Medical Education to outline policies and guidelines that could be used by AMCs to manage industry interactions with AMC physicians, residents, and staff.² The Task Force's report, approved by the AAMC Executive Council in June 2008, made recommendations for policies and procedures relative to the following areas: gifts to individuals; samples; site access by industry representatives; continuing medical education (CME); industry-sponsored programs; industry-sponsored scholarships and education funding; food; travel; ghost-writing; and purchasing.³



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Also in 2008, the American Medical Association's (AMA's) Council on Ethical and Judicial Affairs issued a report entitled "Industry Support for Professional Education in Medicine." The report made several recommendations relative to the interactions that occur between industry and medical professionals, and specifically recommended that AMCs accept no funding for medical education from industry sponsors.

In 2007, the American Medical Students Association released its "PharmaFree Scorecard," grading each U.S. medical school on its conflicts of interest policy or lack thereof.⁴ The Scorecard was updated in 2008 with a detailed analysis of each school's policy and a grade for each, and this detailed review and ranking system was applied again for the 2009 update. The policies are graded on how they approach or treat gifts and financial relationships with industry, samples, purchasing and formularies, sales representatives, educational activities and industry funding, and enforcement. A comparison of the results of the 2008 and 2009 Scorecards indicates that not only are medical schools adopting policies and adding new components to existing policies, but they are also making existing policies more restrictive. Notably, out of the 149 U.S. AMCs, 45 schools received a grade of A or B on the 2009 Scorecard, substantially outstripping the 29 schools receiving As or Bs in 2008.⁵

With these organizations pushing for change, AMCs across the country are adding to the marketing challenges faced by life sciences companies. Although no two AMC interactions policies are identical, many policies address common issues, including: access to facilities or employees, provision of drug and device samples, offering or accepting meals and gifts, use of educational grants and

consulting arrangements, and penalties for non-compliance. In order to provide an overview of the many types of policies and restrictions contained therein, each of these categories is discussed below.

Access

Most policies include a section limiting access to the AMC's facilities and/or medical professionals. Nearly all policies require industry representatives to make an appointment. Many policies limit representatives' access to non-patient care areas and prohibit direct contact with patients unless necessary for training.

The University of North Carolina (UNC) Health Care System policy⁶ specifically prohibits "cold calling" by vendors. Representatives must have an appointment, check in upon arrival at the facility, and wear both UNC and company-supplied name badges while inside. In addition, individual departments at UNC may set time limits on appointments. The UNC policy has a unique provision regarding promotional interactions: industry representatives must inform any UNC staff with whom they interact whether the drug or device at issue is on the UNC formulary, and whether there are any institutional restrictions on its use.

The University of Massachusetts Memorial Medical Center Vendor Access policy⁷ requires representatives to register with a third-party company who manages vendor registration with the Medical Center. In addition, companies must pay an annual fee to the vendor manager (per company, not for each company representative), which ranges from \$25 to \$250 "based on the vendor's risk profile." Also unique to this policy, representatives must provide documentation of a negative tuberculosis test.

Duke University Health System's Pharmaceutical and Nutritional Vendors

Policy⁸ requires that pharmaceutical representatives sign an acknowledgement and agreement to follow the Duke Policy. Representatives must also sign a Confidentiality and Compliance Agreement. This includes standards for maintaining confidentiality and requires that representatives follow Duke's compliance program as it relates to the affirmative obligation to report known or suspected violations of federal and state laws and Duke policies.

Samples

The provision of product samples has long been standard industry practice and an integral component of detailing activities. Many AMCs are now prohibiting samples, or limiting how they can be distributed by industry representatives. For example, the UNC policy⁹ requires each department to appoint an individual who will accept samples. Industry representatives may only interact with the appointed contact person to discuss samples. The University of Michigan Health System policy¹⁰ generally prohibits samples, though vouchers, after being approved by the Ambulatory Formulary Committee, are permissible.

There are a few unique sample restrictions or policies. For example, both the University of Michigan policy¹¹ and the University of New Mexico Health Sciences Center policy¹² prohibit drug samples for inpatient use.

The University of Pittsburgh Medical Center (UPMC) and Schools of Health Sciences launched, in late 2008, a unique sampling program: the "UPMC eSample Center."¹³ As of April 1, 2009, pharmaceutical manufacturers may not provide samples directly to UPMC physicians. Instead, these companies are invited to enroll in the program and then make their samples available "to the physicians of their choice." Physicians, using a web-

based system, can then order samples, vouchers, and coupons for delivery to their clinical practice, which takes from three to six business days.

Food and Gifts

Most policies include either limits or prohibitions on accepting meals and/or gifts from industry representatives, both on- and off-site. For example, the University of Michigan's policy¹⁴ prohibits industry representatives from bringing food, including basic snacks and beverages, into the facility under all circumstances. Those that do not have explicit restrictions or prohibitions frequently include language cautioning medical personnel of the dangers associated, both real and perceived, with accepting gifts, including food, from industry.

The University of Rochester Medical Center in New York has a policy¹⁵ on interactions with the life sciences industry that states: "Personnel may not accept gifts or compensation for listening to a sales talk by an Industry representative." "Sales talk" is not defined in the policy. The policy specifies that gifts of educational materials, such as books, may not be accepted directly, but may be directed to personnel through a general departmental process that reviews the materials for "significant educational value" and de-identifies them as to their source. The policy also notes that anatomical models are permitted, but the cost must be less than \$100. Similarly, the Medical College of Georgia School of Medicine¹⁶ prohibits gifts and compensation for listening to a sales talk by an industry representative. When provided in other contexts, gifts, including meals, must not exceed a fair market value of \$25.

The University of Southern California's (USC's) policy,¹⁷ recently revised and effective September 1, 2009, prohibits all gifts, and specifies that "[e]xisting

branded items may not be utilized in patient-care areas and must be removed." The previous policy¹⁸ had allowed medical professionals, including students and staff, to receive gifts that primarily benefit patients. The prior policy specified that "pens, notepads and other similar small reminder items with company or product logos that have a direct or indirect value to patient" were allowed, and only prohibited branded items in patient care areas. The policy limited gifts from any industry representative to \$50 per year, which meant companies, or the representatives themselves, must track the gifts provided to USC personnel.

The University of New Mexico's policy,¹⁹ approved in early 2008, states: "Beginning January, 2011, meals funded by PHCI [private health care industry] can not be provided on the [University of New Mexico Health Sciences Center] campus. In the transition, departments and divisions will reduce their dependence on PHCI funding by at least 33% in each of the three years." This is a unique approach, at least inasmuch as the reliance on industry funding is acknowledged and a specific timeline is spelled out for implementation of the ban.

Educational Support and Financial Relationships

In addition to limiting interactions with field representatives, several institutions restrict funding for educational programs and consulting arrangements. The policy²⁰ of the Morehouse School of Medicine and Morehouse Medical Associates, Inc. in Georgia prohibits industry funding of internal department meetings, both on- and off-campus, but permits industry funding of medical education. The permitted funding may be directed to a clinical department, but may not be restricted to

a clinical division, specific program, or individual physician.

Several AMCs now prohibit funding that provides meals during education programs. The University of Arizona College of Medicine policy,²¹ for example, prohibits meals, other food, and beverages funded by industry at all activities at the College or its associated clinics.

Numerous institutions specifically prohibit medical professionals from engaging in direct financial relationships with pharmaceutical, medical device and/or biotechnology companies. For example, the University of Massachusetts Memorial Medical Center policy²² prohibits any clinical employee from participating in a speaker bureau.

More often, AMCs permit these relationships but require disclosure to the AMC. The Northwestern University Feinberg School of Medicine policy²³ discourages faculty members from participating in industry-sponsored speaker bureaus. When faculty members do participate in such events, the School's policy requires disclosure within a year of the event date.

Penalties

Violating state or federal laws related to marketing and promotion often results in a hefty civil fine and exclusion from state or federal health plans. While the consequences of violating an AMC policy are generally not as severe, repeated violations often result in exclusion from marketing in the facility, and possibly from interacting with any affiliated healthcare practitioners. Typically, a first-time violation results in a warning or reprimand, and possibly notification to a representative's home office. Sanctions for second and repeated violations typically escalate in severity: the AMC may prohibit the particular representative from accessing the institu-

tion, followed by prohibiting all company field representatives from interacting with medical professionals in the AMC, and finally by prohibiting completely the company from interacting or contracting with all AMC staff. These penalties, while not directly costing the company money and likely not involving much media scrutiny, can cost the company significant opportunities in marketing and collaboration.

Conclusion

It is generally agreed that meaningful and important interactions take place between medical professionals and life sciences industry members and their representatives. Disagreements arise when the conversation turns toward how much oversight and policing is necessary to ensure that these relationships and interactions do not become burdensome, overbearing or unduly influential.

Pharmaceutical, medical device and biotechnology companies serve themselves by having in place procedures that ensure compliance both with federal and state law, and with institution-specific policies. These procedures must identify responsibility for inquiring about and abiding by individual AMC policies and processes. Companies must also monitor and audit the activities of their field representatives to ensure compliance. The burden of following and complying with marketing restrictions and prohibitions may seem overwhelming at times, but staying on top of changes in the marketing landscape will undoubtedly play a significant role in a company's ability to maintain a competitive edge. ▲

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