Marjorie E. Powell
Senior Assistant General Counsel

PhRMA

October 19, 2012

Ms. LouAnn Stanton
Office of the General Counsel
Massachusetts Department of Public Health
250 Washington Street
Boston, MA 02108

RE: Emergency Amendment to Regulations for 105 CMR 970.000, Pharmaceutical and Medical Device Manufacturer Conduct

Dear Ms. Stanton:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments to the Massachusetts Department of Public Health regarding the Department's emergency amendments to the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct. PhRMA is a voluntary, nonprofit association that represents the country's leading biopharmaceutical research companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Last year, America's biopharmaceutical research companies invested $67.4 billion in researching and developing new medicines.

PhRMA believes that the emergency amendments will facilitate the ability of pharmaceutical manufacturers to offer company-sponsored speaker programs that educate and inform health care practitioners about the benefits, risks, and appropriate uses of their products and to engage in other informational discussions with physicians. PhRMA and its member companies would be pleased to provide the Department with any information that would be useful as the Department further considers the emergency amendments.

I. Preemption

PhRMA appreciates the Department's revisions to the disclosure requirements in light of the federal Sunshine Act, which will ensure that patients nationwide have meaningful and relevant information about the relationships between biopharmaceutical and medical device manufacturers and health care practitioners. As you know, the Sunshine Act preempts any state or local law requiring reporting of the same type of information concerning payments or other transfers of value made by applicable manufacturers to covered recipients.[1] In light of the

[1] Social Security Act § 1128G(d)(3).

federal preemption provision, PhRMA agrees with the Department's decision to eliminate the annual disclosure requirement after reporting for calendar year 2012.

Likewise, the emergency amendments provide that companies are deemed to have met most of the quarterly reporting requirements if they comply with the Sunshine Act. However, they are still expected to report the amount expended per participant in attendance at an out-of-office educational presentation. PhRMA believes that this requirement should be similarly eliminated for companies that submit annual reports as required by the Sunshine Act. The Sunshine Act requires applicable manufacturers to report to the Centers for Medicare & Medicaid Services (CMS) payments and transfers of value provided to physicians. As such, applicable manufacturers would be required to report the value of meals and refreshments provided to physicians in attendance at all types of informational presentations, as well as any other items of economic value provided in connection with these programs. This reporting requirement is therefore directly preempted by the Sunshine Act. PhRMA respectfully requests that companies that comply with the Sunshine Act also be deemed to have met this quarterly reporting requirement.

Moreover, PhRMA notes that the per-person amount reported under the emergency amendments could differ from the amount reported under the Sunshine Act if CMS adopts a methodology for allocating the costs of meals that is different from that adopted by the Department. Likewise, suppose a company provides an educational item (e.g., a textbook) to a physician who attends a meal held in connection with an informational presentation. The meal and the educational item would be reported separately to CMS, but they would be reported to the Department as a combined per-person expense. In both of these examples, patients might not understand why the amounts reported are different, which could lead to confusion about the true cost of the meal and the value received by the physician.

II. Content of Company-Sponsored Speaker Programs and Other Product Discussions

The emergency amendments provide that modest meals may be provided to health care practitioners incident to presentations that are conducted out of the office "for the purpose of educating and informing healthcare practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information." Company-sponsored speaker programs provided by pharmaceutical manufacturers are critical to the safe and effective use of prescription drugs because they provide prescribers with current, accurate information about these products.

Companies may also interact with physicians in other contexts, outside of a speaker program, where the focus is on educating health care practitioners about the company's products. For example, a medical science liaison (MSL)[2] might have lunch with a key opinion leader to discuss scientific data related to a product manufactured by the company. Likewise, senior

[2] MSLs are specially trained field personnel with specialized scientific and medical knowledge who communicate primarily with thought leaders and other academicians and general practitioners on a peer-to-peer basis regarding drug products.

marketing personnel within a company may make an informational presentation about the company's products to a group of physicians in a private room in a restaurant.

All company-sponsored speaker programs and other product promotional discussions are subject to the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations of the Food and Drug Administration (FDA), which establish strict standards for materials that manufacturers use to educate practitioners about and promote their medicines. In particular, they require that all claims made during these presentations (1) be supported by "substantial evidence," (2) be truthful and not misleading, (3) contain "fair balance," meaning that efficacy claims must be fairly balanced by applicable safety information, and (4) be consistent with the approved prescribing information for the product. To ensure that company-sponsored speaker programs and other informational presentations comply with these requirements, manufacturers typically have in place a review committee or other mechanism for overseeing the content of these programs. Most companies also actively monitor and audit their speaker programs to ensure compliance with FDA's rules. In addition, companies are required to submit all slide decks used in company-sponsored speaker programs as well as other materials used in connection with informational presentations to the Office of Prescription Drug Promotion (OPDP) within FDA upon first use. Many companies also voluntarily submit draft materials to OPDP for advisory review.

III. Provision of "Modest Meals"

The emergency regulations define "modest meals and refreshments" as "food and or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense." PhRMA appreciates that this definition essentially adopts the standard set forth in the American Medical Association (AMA) Code of Medical Ethics for physicians.[3] This standard is consistent with the PhRMA Code,[4] which provides that "speaker programs may include modest meals offered to attendees and may occur in locations outside of the office or hospital setting, as long as they occur in a venue and manner conducive to informational communication."[5]

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[3] AMA Code of Medical Ethics, § 8.061.

[4] The PhRMA Code has been adopted by 57 companies. Although compliance with the PhRMA Code is voluntary, the Office of the Inspector General (OIG) of the Department of Health and Human Services has specifically cited the PhRMA Code as "a good starting point" for compliance with the anti-kickback laws. 67 Fed. Reg. 62057, 62063 (Oct. 3, 2002). The OIG further stated that compliance with the PhRMA Code "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements." 68 Fed. Reg. 23,731, 23737 (May 5, 2003).

[5] PhRMA Code (2008), § 2. The provision is also consistent with the AdvaMed Code, which provides that "[c]ompanies may provide Health Care Professional attendees with modest meals and refreshments in connection with [product training or educational] programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting." AdvaMed Code (2008) § III. The AdvaMed Code further states that "'[m]odest' means moderate value, but may differ depending on regional differences." *Id.* at Q7.

PhRMA further appreciates that that the definition provides a flexible standard for determining whether a meal is modest, rather than a single dollar ceiling on the cost of the meal. This flexibility is important given that the value of a modest meal may differ depending on the venue and type of meal. For example, meals provided to large groups in a conference center may cost more than meals provided to smaller groups in a neighborhood restaurant. Likewise, PhRMA appreciates that meals should be determined to be modest "as judged by local standards," as the value of a modest meal may vary depending on the locality, even within the state of Massachusetts. This provision is particularly important given that the requirements for the provision of modest meals apply to all meals provided to Massachusetts-licensed health care practitioners, regardless of where the meal takes place. Because the cost of a meal in some U.S. cities is considerably higher than elsewhere in the country, this standard will ensure that companies can provide meals to Massachusetts practitioners, regardless of where they are located.

PhRMA is concerned, however, that this definition could be misinterpreted by some manufacturers as requiring them to conduct an individual assessment as to whether the costs of a particular meal are consistent with what each attendee would pay if dining at his or her own expense. This type of individual assessment would obviously be unworkable. PhRMA therefore recommends that the definition be revised to refer to "what a *typical* health care practitioner might purchase when dining at his or her own expense." Including this additional language would ensure that companies are able to conduct a single evaluation of whether a particular meal is modest.

IV. Disclosure Reports

As noted above, manufacturers that make all required disclosures under the Sunshine Act would be deemed to have met most of the quarterly reporting requirements, though they would still need to file quarterly reports containing the amount expended per participant in attendance at an out-of-office educational presentation. PhRMA appreciates that the Department recognizes the preemptive effect of the Sunshine Act and, as stated above in Section I, urges the Department to similarly eliminate this quarterly reporting requirement for companies that submit annual reports as required by the Sunshine Act.

Moreover, PhRMA believes that the requirement to report the total amount expended per out-of-office educational presentation in section 970.006(4)(c) and the requirement to report the amount expended per participant at an out-of-office educational presentation in section 970.006(4)(d) are unclear as drafted. We assume the Department's intent was for the amount per participant to be calculated by dividing the total amount expended by the number of participants. However, with respect to the amount per participant, the emergency regulations state that the amount reported should "factor[] any meals, refreshments or other items of economic value provided at such presentation."[6] In contrast, the requirement to report the total amount expended is not similarly limited to expenses for meals, refreshments, and other items of economic value

[6] 105 CMR 970.006(4)(d).

and therefore could be read to include overhead expenses, speaker fees, and other costs.[7] As a result, manufacturers would need to use one methodology to calculate the total amount expended for purposes of section 970.006(4)(c) and a second methodology to calculate the total amount expended for purposes of section 970.006(4)(d) (which would then be divided by the total number of participants). PhRMA requests that, if the Department decides such quarterly reporting is still necessary, the Department expressly clarify that both sections 970.006(4)(c) and (d) should be limited to the costs of meals, refreshments, and other items of economic value.

In addition, the emergency regulations do not address how manufacturers should report expenses associated with educational presentations when the audience includes both practitioners licensed in Massachusetts and those licensed in other states. For example, a presentation provided in connection with a national conference could include attendees from many states. PhRMA recommends that manufacturers be permitted to calculate the total expended and amount per participant based on all attendees. Likewise, the emergency regulations do not specify what is meant by the "location" of the presentation. However, PhRMA assumes "location" refers to the city and state of the presentation.

PhRMA requests, therefore, that the Department provide further guidance about the specific nature of the disclosure reports in two ways: (1) by adding several examples to its online FAQs that address hypotheticals such as those provided above and others submitted to the Department as companies begin to implement the disclosure requirement, and (2) by timely issuing a quarterly reporting template that corresponds to the required elements for reporting as set forth in section 970.006(4), particularly since the annual report form does not contemplate reporting of this information. This additional guidance will help companies comply with the disclosure requirement and ensure that the information reported is meaningful to the Department and useful to the public.

In addition, PhRMA requests that the Department promptly provide details regarding submission of the quarterly reports, including when the first report will be due, where the reports should be sent, and how the Department will define a "quarter" (i.e., a calendar quarter or some other three-month period). PhRMA also requests that the Department provide manufacturers with at least 120 days following the conclusion of each quarter to generate, review, reconcile, and submit their reports.

V. Annual Audit

The current regulation requires manufacturers to certify in their annual disclosure reports that they have conducted an annual audit to monitor compliance with the regulation. Because manufacturers are no longer required to submit annual reports, PhRMA requests that the Department clarify whether an annual certification is still required and, if so, how such certification should be made.

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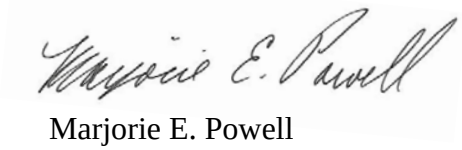
[7] *Id.* 970.006(4)(c).

We would be happy to discuss these recommendations in further detail if you have questions.

Sincerely,



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