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BOSTON, Dec. 10, 2008 — The Massachusetts Public Health Council (PHC) today released proposed regulations that will put Massachusetts at the forefront of regulating sales and marketing practices of the pharmaceutical and medical device industry. The new rules will also mandate broad public disclosure of fees, payments and other compensation by companies to health care providers.

The proposed rules were presented at the monthly meeting of the PHC and released for a public comment period that will include two public hearings in January.

“These new rules will add to a growing list of initiatives that Massachusetts has undertaken to support quality and control costs in health care,” said Massachusetts Department of Public Health (DPH) Commissioner John Auerbach. “Our goal in drafting these regulations was to uphold the intent of the law passed by the Legislature and signed by Governor Patrick last August; namely, to curb any inappropriate influence of industry sales and marketing activities on the independent clinical judgment of health care providers in the Commonwealth. We also wanted to strike a balance by promoting broad transparency of financial dealings between the industry and health care providers, while at the same time recognizing important and legitimate research occurring in Massachusetts,” he said.

Commissioner Auerbach noted that of the six states and the District of Columbia that currently regulate various activities of pharmaceutical and medical device companies, none go as far as what is required under the proposed rules announced today. Massachusetts will also be the first state to require disclosure by medical device companies.

Under the proposed regulations Massachusetts would be the:

Only state to require adoption of and compliance with a state-authored Marketing Code of Conduct, which will detail activities that are banned and those that are permitted under the law.

Only state to prohibit certain payments to health care providers by both pharmaceutical and medical device manufacturers.

Only state to require financial disclosures by medical device manufacturers.

Only state to require disclosure of free drug samples and the provision of medical equipment for demonstration or evaluation purposes.

One of only two states to make disclosure data part of the public record.

State with the broadest definition of “Sales and Marketing” in the nation.

Massachusetts is the first state to define its own code of conduct that sets out guidelines for the interaction between Massachusetts health care providers and industry representatives. The code expressly prohibits certain activities and in some cases places restrictions on how activities may be conducted.

What are some of the activities that will be prohibited or restricted?

Payment for entertainment or recreation is prohibited, such as tickets to a sporting event, passes to a museum, etc.

Payments in cash or cash equivalents to health care providers, either directly or indirectly, are prohibited, except as compensation for bona fide services.

Complimentary items such as pens, mugs, and calendars are banned.

Meals are heavily restricted and in some instances prohibited. For example, any meals given to health care providers must be modest, and only provided at a training or educational event. They cannot be provided or paid for when they occur outside of a health care provider's office or the hospital setting. Meals to spouses or other guests are prohibited. The rules would also allow for industry to sponsor conferences and professional meetings; however companies cannot dictate how that funding is spent.

The new rules would exempt from disclosure payments made to health care providers for genuine research projects and clinical trials. However, all other payments of \$50 or more would need to be disclosed publicly. The new rules would have an implementation date of July 1, 2009, and require the submission of information under public disclosure annually by July 1, 2010. The disclosed financial information will be posted on a searchable public web site.