



September 28, 2012

Commissioner John Auerbach
Massachusetts Department of Public Health
250 Washington Street
Boston, MA 02108

Re: 105 CMR 970.000, Pharmaceutical and Medical Device Manufacturer Conduct

Dear Commissioner Auerbach,

We appreciate the opportunity to comment on 105 CMR 970.000, the emergency regulation to implement amendments to Chapter 111N of the General Laws, also known as the Pharmaceutical and Medical Device Gift Ban and Disclosure Law, or the “gift ban law.”

We write to you on behalf of the Massachusetts provider community with concern over the lack of a patient-centered, community-focused approach in the emergency gift ban regulations on conflict of interest issued on September 19th by the Commonwealth’s Department of Public Health.

As physicians, we are deeply disappointed that these regulations undermine the State’s leading commitment to evidence-based prescribing and to the protection of patients from the dangers of undue marketing influence in our profession. The new emergency regulations accommodate industry interests at real expense to patient safety and will result in a high financial cost to the state’s health care budget.

Representing physicians across medical specialties, the National Physicians Alliance (NPA) is united in support of unbiased, evidenced-based education and clinical practice. Marketing interests should not supersede this foundational obligation to patients. Indeed, Massachusetts has been a leader in recognizing the need for regulation in this area through passage of the State’s 2008 landmark gift ban legislation.

We therefore call on the DPH to put greater emphasis on public health by enacting the following regulations in place of the current emergency regulations:

1. Choose a specific dollar amount to define a “modest meal”, preferably by adoption of the established per diem reimbursement rates for state and federal employees to define “modest.”
2. Adopt a monetary cap per health care practitioner, per event.
3. Prohibit pharmaceutical marketing funds to be used to purchase alcohol for providers.

We also ask the DPH to examine and incorporate a larger selection of codes of conduct in developing or revising regulations in this area. In selecting only the AMA Code of Ethics as a provider organization benchmark, the DPH has not fully met its responsibility to incorporate a thorough, representative set of standard codes of ethical conduct that govern prescriber relations with industry. Multiple Massachusetts

medical schools, hospitals, and provider organizations have adopted codes of conduct which promote integrity, professionalism, and a commitment to patient-focused, evidence-based medicine in a much more comprehensive fashion than do the current regulations. These policies prohibit gifts from industry, including all onsite and most offsite industry-sponsored meals, with some exceptions for meals associated with CME events. We urge DPH to broaden the scope of codes considered as benchmarks for the establishment of the Commonwealth's own code. We will be happy to provide more specific suggestions and language upon request. Please find our own relevant resources online at www.npalliance.org, specifically through our Unbranded Doctor materials.

In addition, we urge the DPH to reinsert non-duplicated state expense reporting requirements for all prescribers and to make these available in a form and forum widely available, useful, and understandable to the public of the Commonwealth.

Again, we appreciate your consideration of our comments on emergency regulation 105 CMR 970.000 and would welcome the opportunity to work with you in revising the current code. If the NPA can be of assistance, please contact Dr. Mary Carol Jennings at 864.992.3391 or mary.carol.jennings@npalliance.net.

Sincere regards,

Mary Carol Jennings, MD, Member-Elect, NPA Board of Directors [Boston MA]
Constance Liu, MD, PhD, NPA Regional Representative [Boston MA]
Valerie Arkoosh, NPA President [National Office]
Jean Silver-Isenstadt, MD, PhD, NPA Executive Director [National Office]

cc:

Governor Deval Patrick
Mo Cowan, Chief of Staff, Office of the Governor
Kate Cook, Director of Cabinet Affairs, Office of the Governor
Rosemary Powers, Senior Director of Government Affairs, Office of the Governor
JudyAnn Bigby, Secretary of Health and Human Services
Suzanne Cray, Deputy Chief of Staff, Executive Office of Health and Human Services
Erin McAleer, Legislative Director, Executive Office of Health and Human Services
Donna Levin, General Counsel, Massachusetts Department of Public Health
Dianne Morad, Legislative Director, Massachusetts Department of Public Health
Iyah Romm, Director of Policy, Health Planning and Strategic Development, Bureau of Health Care Safety and Quality, Massachusetts Department of Public Health