MITA®
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

February 19, 2016

The Honorable Kristen Lepore
Secretary of Administration and Finance
Executive Office for Administration and Finance
State House, Room 373
Boston, MA 02133

Re: Governor Baker's Executive Order No. 562.

Dear Secretary Lepore:

As the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) appreciates the opportunity to comment on the Commonwealth of Massachusetts' regulatory reform efforts. Specifically, we are offering comments on 105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct. It is MITA's belief that 105 CMR 970.000 should be rescinded under the standards Governor Baker established in Executive Order No. 562.

* * * *

With a national standard now in place, the Massachusetts Code of Conduct and its related reporting requirements have become unnecessary. MITA established a code of ethics a number of years ago, subscribed to by our member companies who manufacture medical imaging and radiation therapy equipment, that mirror the best practices for health care compliance established by the United States Department of Health and Human Services. Interactions either banned or limited by the Massachusetts Code of Conduct (e.g., sham consulting payments, non-business travel, gifts) are forbidden under our industry's code of ethics. Indeed, any company that engages in these practices risks civil and criminal prosecution by federal and state agencies. Lastly, because of the US Sunshine Act, companies have established universal rules regarding interactions with health care professionals, knowing that in this era of transparency, every transfer of value may be made public.

Executive Order No. 562 established several standards for rescinding a regulation. Our comments above address two:

1. There is no longer a clear need for government intervention best addressed by a Massachusetts Agency or governmental body;
2. The regulation exceeds federal requirements and duplicates other efforts.

Additionally, 105 CMR 970.000 fails to meet these other standards:

1. The costs of the regulation exceeds the benefits. National laws and industry codes make the Code of Conduct no longer of clear benefit to the citizens of the Commonwealth.
2. Less restrictive or intrusive alternatives have not been explored in light of changing industry standards and federal laws like the US Sunshine Act.
3. The regulation unduly and adversely affects the citizens of the Commonwealth by creating a confusing and limiting law that restricts manufacturers' ability to provide important information to Massachusetts health care professionals regarding the safe and effective use of products.
4. There is no process for measuring the effectiveness of the regulation.

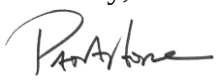
Finally, from a business perspective, the regulation is burdensome and adversely affects the ability of MITA members to provide information about how our products can lower cost and increase outcomes. Three years since adoption, the Executive Office of Health and Human Services, which administers 105 CMR 970.000, has failed to establish a process to report meals to health care professionals. A notice on its website from May 2014 indicates that the process is forthcoming. These facts indicate that this regulation is already being ignored. But some of our members cannot legally determine whether the regulation remains in effect, limiting their ability to provide necessary information to Massachusetts physicians and other health care professionals.

For these reasons, MITA urges that 105 CMR 970.000 be rescinded.

* * * *

We thank you for including stakeholders in this regulatory review process, and MITA looks forward to assisting in making Massachusetts a safe, health, and effective place to do business. If you have any questions, please feel free to contact Cassandra Ricci at 703-841-3228 or by email at cricci@medicalimaging.org.

Sincerely,



Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.