

## **S 2660 Imposes Harmful Restrictions on Medicine in Massachusetts**

Section 26 of Senate Bill 2660 would prohibit a “pharmaceutical or medical device manufacturer agent” from giving a gift of any value to a health care practitioner (HCP), a member of an HCP’s immediate family, an HCP’s employee or agent, a health care facility, or the employee or agent of a health care facility. While intended to protect the integrity of the doctor/patient relationship, the bill goes far beyond prohibiting those gifts that the bill’s supporters think might improperly influence a physician’s medical judgment, and it will likely limit other important activities that significantly benefit patients. Following is an overview of the key problems in the way Section 26 is written.

### ***Samples are not clearly excluded.***

Under the definition of “gifts,” Section 26 exempts “prescription drugs provided to a physician solely and exclusively for use by...patients.” This is likely intended to include samples, but doesn’t explicitly. Nor does this definition clearly address medical device samples or demonstration devices.

### ***Physicians and patients will lose access to valuable information.***

Drug companies will be prohibited from providing HCPs and health care facilities with patient education and disease management materials. The legislation’s exception for peer-reviewed academic, scientific, or clinical information is insufficient because patient-directed materials and even some articles in scientific journals are not peer-reviewed. This prohibition would also affect the following other educational materials and programs:

- Anatomical models and charts for HCPs’ offices.
- Continuing Medical Education (CME) programs funded by pharmaceutical manufacturers. (This prohibition directly contradicts guidelines espoused by the FDA, the HHS Office of the Inspector General (OIG), the AMA, and the Accreditation Council for Continuing Medical Education (ACCME).
- Risk Evaluation and Mitigation Strategies (REMS) programs mandated by the FDA for certain high-risk medicines to safeguard patient safety.

### ***Medical Research in Massachusetts will be Stifled.***

Section 26 prohibits research grants provided to physicians. The NIH currently lists **5,167 clinical trials** in Massachusetts alone. Of these trials, **1,786** are currently recruiting patients. Conducting an investigator-sponsored clinical trial would arguably not constitute “consideration” for a research grant, and thus the grant would be unlawful. Physicians in Massachusetts would be prevented from conducting important research, and patients in Massachusetts might have to go to other states to participate in clinical trials.

### ***Individuals and groups outside of the pharmaceutical manufacturer/HCP relationship will be affected.***

As written, the gift ban could restrict the activities of individuals who are far removed from either the drug manufacturer or the HCP or health care facility. For example, the ban would prohibit someone at a design firm who works on a pharmaceutical account from offering a cup of coffee to a friend who happens to work for the accounting company engaged by a hospital.

Section 26 also ignores the fact that an HCP’s family member might be employed by a pharmaceutical company, and the legislation could prohibit the family member from accepting a bonus or other job perks.

In addition, patient groups associated with HCPs or their family members could not accept sponsorship from pharmaceutical companies.