

The S 2660 Section 26 - Pharmaceutical Gift Ban Will Stifle Medical Research

Massachusetts is home to some of the most important medical research being conducted in the United States, including 5,167 clinical trials currently underway or shortly to begin. New legislation being considered by the Massachusetts legislature—Section 26 of Senate Bill 2660—would place significant restrictions on the ability of researchers to obtain critical funding, recruit patients for clinical trials, and compete with researchers in other states not subject to the same restrictive prohibitions. Specifically, this legislation prohibits 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.

The legislation would allow specific payments for services rendered but require pharmaceutical and medical device manufacturing companies to disclose all these payments to HCPs or health care facilities. The intention is to lower health care costs and protect the integrity of the provider/patient relationship; however, the likely result will be increased paperwork, decreased innovation, and significant obstacles to Massachusetts’ ability to attract medical studies to the state.

S 2660 will discourage investment in education and research.

Several measures in the legislation will increase the costs of research and make investment, financing, and marketing more difficult, including:

- Researchers will be prohibited from engaging in any activity perceived as “marketing,” which could include speaking on behalf of a drug at various stages in the development process.
- Gifts are banned unless consideration of equal or greater value is received and there is a specific deliverable restricted to medical or scientific issues. Evaluation of research for possible venture funding isn’t a strictly medical or scientific issue, and it therefore becomes a suspect activity, as does anything interpreted as marketing, including physician participation in pharmaceutical-funded Continuing Medical Education (CME) programs.
- 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.
- Companies would be forced to keep records of every transaction they do with every HCP in the state—a particularly onerous burden for small companies or niche products.
- Research institutions will have to report down to the provider level how much “benefit” they received from the grant, which would divert funding from research itself to reporting and distribution.

S 2660 will expose manufacturers and HCPs to unnecessary public scrutiny.

Any payments or economic benefits not prohibited by the ban would have to be reported, along with specific information about the recipients of such “benefits.” This information would become public record on the Department of Health website unless it is considered a protected trade secret. The identity of “gift” recipients does not fall under that protection. In addition, any physician who participates in research or consults with a company on early drug development will have his or her income posted in an online database where it would be readily accessible to trial lawyers and the media.

Mandatory disclosure of gifts, fees, and payments that are part of legitimate business relationships not only exposes researchers to serious personal and professional risks, but could also give competitors proprietary information and lead to an overall decrease in competition.