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Firms win victory on doctor gift rules

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Draft doesn't seek research funds data

By Liz Kowalczyk, Globe Staff | December 6, 2008

Payments by drug and medical device companies to physicians for research and certain types of consulting will be exempt from public disclosure requirements in the state's sweeping new law to clamp down on industry influence over doctors, according to draft regulations obtained by the Globe.

Consumer advocates have been pushing for rules that require companies to disclose the full nature of their relationships with physicians, but biotechnology and pharmaceutical companies have been lobbying the Department of Public Health, which wrote the regulations, to exempt the disclosure of payments to doctors for research and research-related activities, arguing that such public scrutiny would scare off companies from funding clinical trials in Massachusetts.

In the proposed regulations, the department states that it sought to limit undue industry influence over physicians' prescribing behavior while not hampering research and requiring disclosure of trade secrets.

Even so, an official in Governor Deval Patrick's administration said yesterday that the proposed regulations would give Massachusetts the strictest law in the country, in terms of banning all gifts to doctors of merchandise, entertainment, and tickets to sporting events; restricting complimentary meals and travel; and requiring public disclosure of payments of at least \$50 for marketing activities.

Companies will be required to disclose payments, for example, for speaking to other physicians about a company's products and consulting on the marketing of drugs and devices.

"We believe these rules are going to be the toughest in the nation," said the official, who did not want to be named because the regulations are not supposed to be made public until next week. "There are people who are going to say we went too far and people who will say we didn't go far enough. When this happens, it usually means you've struck the right balance."

Health Department staff plan to present the proposed regulations to the Public Health Council next Wednesday and will hold two public hearings on the plan before the council takes a final vote in February.

Senator Mark C. Montigny, a New Bedford Democrat who has pushed for years to ban industry gift-giving, said he was extremely disappointed in the plan and called the proposed regulations "a cave-in to Big Pharma."

"That is a significant gutting of the bill if they don't have to report research," he said. "There are so many ways to get around [disclosing] this relationship. To me, the simplest way to protect the consumer is full disclosure."

The law the Legislature enacted this summer does not explicitly exempt payments for research, saying companies should disclose "any fee, payment, subsidy, or other economic benefit." But it directs the health department to write regulations guiding implementation of the law.

In a memo intended for the Health Council next week, department staff said they believe the intent of the law is to regulate marketing behavior, partly because the regulation also establishes a marketing code of conduct.

Researchers who study industry influence on physicians have increasingly turned their attention to payments for research, however, and several studies have found that a clinical trial sponsored by a drug company is more likely to result in positive findings for that company's drug.

Doctors whose labs are heavily dependent on funding from certain pharmaceutical companies may come to feel indebted to those companies, drug industry critics say. But because medicine generally is dependent on industry for funding of research, many specialists recommend that the doctor disclose this funding, not reject it altogether.

Robert Coughlin, president of the Massachusetts Biotechnology Council, told public health officials that companies would be less likely to pay for clinical trials in Massachusetts if they are subject to disclosure rules here not found in most other states.

"We don't want these regulations to harm innovation," he said in an interview yesterday. "This is competitive and proprietary information."

In August, Patrick signed into law one of the nation's strictest limits on gifts given to medical professionals by drug sales people, the most contentious measure contained in a broad package intended to improve healthcare safety and curb skyrocketing costs. The changes were made amid intense focus on the cost and quality of healthcare, which consumes 1 in every 6 dollars spent in Massachusetts.

The limits on drug and device companies put Massachusetts at the forefront of states in cracking down on the use of financial incentives to persuade doctors to prescribe particular drugs or medical devices, a practice that can needlessly drive up costs.

The draft rules would require drug and medical device companies doing business in Massachusetts to comply with industry marketing codes of conduct by July 1, 2009, and to file their initial annual reports of physician payments on July 1, 2010, covering marketing-related payments for the preceding year. The rules don't state when the data would be made public, but firms that fail to comply with the law would be fined \$5,000 per violation.

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