HB 818

Department of Legislative Services

Maryland General Assembly
2011 Session

FISCAL AND POLICY NOTE

House Bill 818 (Delegates Kipke and Hammen)
Health and Government Operations

Manufacturers of Prescribed Products - Payments to Health Care Professionals - Prohibition

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This bill prohibits a "manufacturer" from offering or giving any "gift" to a "health care professional," with specified exceptions. A violation of the prohibition is subject to existing criminal and civil penalties under the Maryland Food, Drug, and Cosmetic Act. The Department of Health and Mental Hygiene (DHMH) is authorized to adopt regulations to carry out the provisions of the bill.

Fiscal Summary

State Effect: Assuming concerted enforcement of the bill's prohibition, DHMH expenditures increase by as much as $130,100 in FY 2012, which reflects the bill's October 1, 2011 effective date, for personnel and administrative expenses. Potentially significant increase in revenues and minimal increase in expenditures due to application of existing penalty provisions. Regulations can be promulgated using existing DHMH budgeted resources. Future years reflect annualization and inflation.

(in dollars)	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
GF Revenue	-	-	-	-	-
GF Expenditure	$130,100	$161,500	$169,900	$178,700	$188,100
Net Effect	($130,100)	($161,500)	($169,900)	($178,700)	($188,100)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: Revenues and potentially expenditures increase minimally due to application of existing penalty provisions.

Small Business Effect: None.

Analysis

Bill Summary: "Gift" means any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care professional without fair market value reimbursement. "Health care professional" is an individual licensed or certified under the Health Occupations Article and authorized to prescribe or recommend prescribed products. Health care professional includes partnerships or corporations composed of health care professionals or an officer, employee, agent, or contractor of health care professionals. "Manufacturer" means a pharmaceutical, biological product, or medical device manufacturer or any other person engaged in the production, preparation, propagation, compounding, processing, packaging, repackaging, distributing, or labeling of prescribed products. Manufacturer includes wholesale distributors that hold permits from the State Board of Pharmacy, but does not include licensed pharmacists.

The bill's prohibition does not apply to:

- samples for free distribution to patients;
- loan of a medical device for a trial period of up to 180 days to permit evaluation of the device by the health care professional or patient;
- peer-reviewed academic, scientific, or clinical articles or journals that serve a genuine educational function provided to health care professionals for the benefit of patients;
- scholarships or other support for medical students, residents, and fellows to attend certain "significant educational, scientific, or policy conferences or seminars;"
- payments to the sponsor of "significant educational, scientific, or policy conferences or seminars" under specified circumstances;
- payment for a government-sponsored educational, scientific, or policy conference or seminar under specified circumstances;
- honoraria and payment of the expense of a health care professional who serves on the faculty at a "significant educational, scientific, or policy conference or seminar" under specified circumstances;
- direct and indirect costs of a bona fide clinical trial;
- direct and indirect costs, including direct salary support and necessary expenses, of certain research projects;
- payment for bona fide scientific consulting under specified circumstances;
- payment or reimbursement for the reasonable expenses, including travel and lodging, necessary for technical training of a health care professional on the use of a medical device under specified circumstances;

- royalties and licensing fees paid to a health care professional in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care professional holds an ownership right; and
- health care products donated to a public or private nonprofit educational or health care organization or institution for training or free distribution to patients or the public, if the donation does not require the organization or institution to purchase a prescribed product.

Current Law: There are no provisions prohibiting gifts from pharmaceutical manufacturers under State law.

The federal Patient Protection and Affordable Care Act (ACA) requires drug and medical device manufacturers to annually report gifts and payments made to physicians and teaching hospitals beginning January 1, 2012. The Secretary of the U.S. Department of Health and Human Services will post the information on a public website. Disclosure of payments is required, whether cash or in-kind transfers, including compensation; food, entertainment, or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; and any other transfer of value.

Under § 21-1215 of the Health-General Article, a person who violates any provision of the Maryland Food, Drug, and Cosmetic Act is guilty of a misdemeanor and on conviction subject to a fine of up to $10,000 and/or imprisonment for up to one year. Repeat offenses are subject to a fine of up to $25,000 and/or imprisonment for up to three years. In addition to criminal penalties, an individual may be enjoined from continuing the violation and a civil penalty of up to $5,000 applies in an action in any District Court.

Background: According to the Kaiser Family Foundation, national spending on prescription drugs was $234.1 billion in 2008, nearly six times the $40.3 billion spent in 1990. Although prescription drug spending has been a relatively small proportion of national health care spending, it has been one of the fastest growing components. In 2007, Marylanders spent $5.6 billion for prescription drugs, 16% of total health care expenditures in the State.

The pharmaceutical industry spends nearly $30 billion annually on marketing, the majority of which is spent on direct marketing to physicians. A December 2010 U.S. Senate Finance Committee staff report brought to light questionable transactions between Abbott Laboratories, a manufacturer of cardiac stents, and a cardiologist formerly employed by St. Joseph Medical Center. The staff report documents consulting fees paid to the doctor and also reimbursement for a barbecue and crab feast held at the doctor's home.

This bill is similar to draft model legislation created by the Pew Prescription Project and legislation enacted in Vermont. Two other states, Massachusetts and Minnesota, have also enacted legislation prohibiting, to some degree, gifts from pharmaceutical manufacturers to health care professionals.

The University of Maryland Medical School and Johns Hopkins Medicine both have internal professionalism policies regarding such issues as gifts to individuals, pharmaceutical samples, site access by pharmaceutical and device manufacturer representatives, and industry-sponsored events. These policies are somewhat consistent with, though not identical to, this bill.

State Fiscal Effect: Although not specified in the bill, Legislative Services assumes that regulations will establish framework for enforcement of the bill, which will be carried out by DHMH's Office of the Inspector General. There is not sufficient personnel for this purpose now. Therefore, general fund expenditures increase by as much as $130,130 in fiscal 2012, which accounts for the bill's October 1, 2011 effective date, to hire two full-time investigators and one part-time support staff to enforce the bill's prohibition. This estimate includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. To the extent that there are few violations of the prohibition, general fund expenditures may be reduced.

New Permanent Positions	2.5
Salaries and Fringe Benefits	$117,601
One-time Start-up Costs	11,460
Other Operating Expenses	1,069
Total FY 2012 State Expenditures	**$130,130**

Future year expenditures reflect full salaries with 4.4% annual increases and 3% employee turnover as well as 1% annual increases in ongoing operating expenses.

Legislative Services does not anticipate significant incarceration costs under this bill. However, as violations of the bill's prohibition are subject to a fine of up to $10,000 and a civil penalty of up to $5,000, general fund revenues likely increase, potentially by a significant amount, due to enforcement efforts.

Additional Information

Prior Introductions: SB 537/HB 548 of 2003 would have prohibited a physician, nurse practitioner, or pharmacist from accepting any gift greater than $50 from a pharmaceutical manufacturing company or a pharmaceutical marketer, with the exception of samples and literature pertaining to pharmaceutical products. SB 537 received an unfavorable report from the Senate Education, Health, and Environmental Affairs Committee. Its cross file, HB 548, was heard by the House Health and Government Operations Committee, but no further action was taken on the bill.

Cross File: None.

Information Source(s): Kaiser Family Foundation, the Pew Prescription Project, Department of Health and Mental Hygiene, Department of Legislative Services

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mc/mwc

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