HB 519

Department of Legislative Services

Maryland General Assembly
2004 Session

FISCAL AND POLICY NOTE

House Bill 519 (Delegate Boutin, *et al.*)
Health and Government Operations

Pharmaceuticals - Marketing - Disclosure and Registration

This bill requires pharmaceutical manufacturers by January 1 of each year to disclose to the Board of Pharmacy any economic benefits connected with their marketing efforts to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or individual in the State authorized to prescribe, dispense, or purchase prescription drugs. By the same date, pharmaceutical manufacturing companies also must disclose the name and address of any marketers working on their behalf in Maryland. Pharmaceutical marketers must register with the board before practicing in Maryland. The bill sets penalties for noncompliance with disclosure requirements and requires the board, in consultation with the Office of the Attorney General (OAG), to adopt regulations by December 1, 2004. OAG must report on the disclosures by July 1 annually to the Governor and the General Assembly.

The bill takes effect July 1, 2004.

Fiscal Summary

State Effect: Special fund expenditures for the board could increase by $81,300 in FY 2005 to hire one full-time administrative specialist and one part-time Assistant Attorney General. Special fund revenues could increase by $228,000 in FY 2006 if an estimated 570 pharmaceutical marketers register. Special fund revenues could be higher to the extent that the manufacturers employ more marketers. Future years reflect biennial fee revenue, annualization, and inflation.

(in dollars)	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
SF Revenue	$0	$228,000	$0	$228,000	$0
SF Expenditure	81,300	94,700	99,900	105,600	111,600
Net Effect	($81,300)	$133,300	($99,900)	$122,400	($111,600)

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: A pharmaceutical manufacturing company is defined as an entity that produces, prepares, propagates, compounds, converts, or processes prescription drugs or packages, repackages, labels, relabels, or distributes prescription drugs. Wholesale drug distributors and licensed pharmacists are excluded.

A pharmaceutical marketer is defined as a person employed by or under contract to represent a pharmaceutical manufacturing company who engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in Maryland to any physician; hospital; nursing home; pharmacist; health benefit plan administrator; or individual authorized to prescribe, dispense, or purchase prescription drugs. This excludes wholesale drug distributors or distributor representatives who promote or market a distributor's services in connection with a prescription drug.

A pharmaceutical manufacturer's marketing activities disclosure must be made on a board-prescribed form and permit the company to identify trade secret information. The board and OAG must keep all trade secret information confidential. The following information is exempt from disclosure:

- free prescription drug samples intended for patient distribution;
- the payment of reasonable compensation and expense reimbursement for clinical trials conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using unknown treatments;
- any gift, fee, payment, subsidy, or other economic benefit with a value of less than $25; and
- scholarships or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional association if the recipient is selected by the association.

A pharmaceutical marketer must register with the board before practicing in the State. Upon registration, each marketer must certify that he or she will adhere to the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals. The board will collect a $400 fee per marketer every two years. All fees will be distributed to the board.

If a company fails to disclose the required information, OAG may bring an action for injunctive relief, including costs and attorneys' fees against the company and impose a civil penalty of up to $10,000 for each violation. Each failure to disclose the required information will be a separate violation.

Current Law: The board currently does not monitor pharmaceutical marketing activities in the State. Chapter 157 of 2002 repealed the board's requirement that pharmaceutical manufacturers must have a State permit.

Background: In fiscal 2003 there were 57 pharmaceutical manufacturers operating in Maryland, the last data available from the Department of Health and Mental Hygiene. A specific number of pharmaceutical marketers employed by these manufacturers is not available.

This bill is based on a similar provision in Vermont legislation enacted in 2002. The PhRMA code states that interactions between manufacturers and health care professionals should be focused on providing scientific, educational, and product information and supporting medical research and education.

State Revenues: No effect in fiscal 2005. Legislative Services assumes the board would not begin collecting the fee revenue until fiscal 2006. Special fund revenue to the board could increase by $228,000 biennially beginning in fiscal 2006, assuming there are 57 pharmaceutical marketers operating in Maryland and each employs at least 10 marketers, each paying a biennial $400 fee. Special fund revenues could be higher to the extent that the bill broadly defines who is considered a marketer. A specific number of pharmaceutical marketers working in the State was not available.

State Expenditures: Special fund expenditures could increase by an estimated $81,337 in fiscal 2005, which accounts for a 90-day start-up delay. This estimate reflects the cost of hiring an administrative specialist to issue the pharmaceutical manufacturer registrations, collect the pharmaceutical manufacturer disclosure statements, and develop regulations. It also includes a part-time Assistant Attorney General to assist in developing regulations, create the annual report, and conduct investigations into any pharmaceutical manufacturers not in compliance with the bill's requirements. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Salaries and Fringe Benefits	$66,096
Operating Expenses	15,241
Total FY 2005 State Expenditures	**$81,337**

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 3% employee turnover; and (2) 1% annual increases in ongoing operating expenses.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Office of the Attorney General, Pharmaceutical Research and Manufacturers of America, Department of Health and Mental Hygiene, Department of Legislative Services

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