

Department of Legislative Services
 Maryland General Assembly
 2009 Session

FISCAL AND POLICY NOTE
 Revised

House Bill 574 (Delegate Hubbard, *et al.*)
 Health and Government Operations

Prescription Drugs - Evidence-Based Prescriber Education and Outreach Program

This bill establishes an Evidence-Based Prescriber Education and Outreach Program within the Department of Health and Mental Hygiene (DHMH) to provide health care professionals with evidence-based information to support prescription drug prescribing decisions. In addition, the bill establishes an Evidence-Based Prescriber Education and Outreach Program Fund, administered by DHMH, to support the program.

Fiscal Summary

State Effect: Special fund revenues increase beginning in FY 2010 as fees are collected from pharmaceutical manufacturers and labelers doing business in the State. Fee revenues cannot be reliably estimated at this time. Special fund expenditures increase by \$277,100 in FY 2011 to hire eight full-time equivalent (FTE) employees to gather and analyze comparative effectiveness drug studies, provide health care professionals with one-on-one information and education regarding the comparative effectiveness of prescription drugs, and support the administrative operations of the program. Future year expenditures reflect annualization and inflation as well as the potential need for general fund support to ensure a viable program. DHMH can administer the *fund* with existing resources.

(in dollars)	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
SF Revenue	-	-	-	-	-
SF Expenditure	\$0	\$277,100	-	-	-
GF/SF Exp.	\$0	\$0	\$937,400	\$981,700	\$1,028,200
Net Effect	\$0	(\$277,100)	(\$937,400)	(\$981,700)	(\$1,028,200)

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: The program begins April 1, 2011, and is subject to available funding. DHMH, in consultation with the Maryland Board of Physicians and the State Board of Pharmacy, must work with the University of Maryland School of Pharmacy to develop, implement, and promote the program. The School of Pharmacy may be contracted to administer the program as well.

The program must provide health care professionals authorized to prescribe or dispense prescription drugs with information and education on the comparative efficacy, safety, and cost-effectiveness of prescription drugs. This must be done primarily through in-person outreach and education sessions in the professional's workplace. Further, the information must be provided to professionals who participate in, contract with, or are reimbursed by State health care programs. It may also be provided to other health care professionals if funding permits or for a fee.

The bill requires that informational and educational materials, as well as individuals conducting outreach and education sessions under the program, meet certain standards of quality and objectivity.

The Evidence-Based Prescriber Education and Outreach Program Fund consists of a \$2,500 annual fee collected from pharmaceutical manufacturers and labelers; money appropriated in the State budget; and any money from other sources. Manufacturers and labelers doing business in the State have to start paying the annual fee beginning April 1, 2010. DHMH may reduce the fee of any manufacturer or labeler whose volume of business in Maryland justifies a fee reduction. Fund expenditures must be made in accordance with the State budget.

Current Law: State law does not specifically address prescribing habits.

Background: Evidence-based prescription drug research has been used increasingly as a way to compare the effectiveness and safety of prescription drugs within the same class, apply that information to prescribing decisions, and improve health outcomes. A drug class is a group of medications that tend to work in the same way, have a similar chemical structure, or are used to treat the same health condition.

At the federal level, the Agency for Health Research and Quality (AHRQ) established a network of Evidence-based Practice Centers (EPCs) that conduct comparative effectiveness reviews of medications, devices, and other health care interventions. EPCs use the reviews to help public and private-sector organizations improve the quality of health care.

At the state level, the Center for Evidence-Based Policy within the Oregon Health and Science University operates the Drug Effectiveness Review Project (DERP). DERP obtains the best available evidence to conduct reviews on the effectiveness and safety of drugs in the same class. Many participating states use DERP reviews to shape drug formularies in state programs like Medicaid. Current DERP participants include Arkansas, Canadian Agency for Drugs and Technologies in Health, Idaho, Kansas, Oregon, Michigan, Minnesota, Missouri, Montana, New York, North Carolina, Washington, Wisconsin, and Wyoming.

In addition, Consumer Reports operates a public education project of Consumers Union called *Best Buy Drugs*. The project bases its reports and recommendations, available on its web site, largely on DERP reviews and current drug prices.

State Fiscal Effect: Special fund revenue for the Evidence-Based Prescriber Education and Outreach Program Fund increases beginning in fiscal 2010 as fees are collected from pharmaceutical manufacturers and labelers doing business in the State starting April 1, 2010. Special fund revenues may also increase if money is included in the State budget for the fund, if any other money from other sources is accepted by the fund, or if the University of Maryland charges a fee for education provided to health care professionals who do not participate in, contract with, or receive reimbursement from State health care programs. However, under the bill, the university may not charge a fee for education provided to health care professionals who participate in, contract with, or are reimbursed by State health care programs.

While DHMH can administer the *fund* with existing resources, general fund expenditures may be needed to capitalize the *program*. Legislative Services advises that revenue generated by assessing manufacturers is unlikely to cover program costs, and that revenue generated from fees charged for education provided to health care professionals who do not participate in, contract with, or receive reimbursement from State health care programs is likely to be minimal. The university estimates that fees may generate about \$225,000 per year, which equates to 90 manufacturers and labelers paying the \$2,500 fee. However, it is difficult to reliably estimate the number of manufacturers and labelers subject to the fee as Chapter 157 of 2002 eliminated the requirement for a State pharmaceutical manufacturing permit. Thus, the ability to track the number of manufacturers in the State was also eliminated, nevertheless, in 2001, 52 manufacturers held permits.

Legislative Services advises that annual revenue generation of around \$225,000 is not sufficient to cover a program that conducts one-on-one education to health care providers throughout the State. This is true despite the fact that DHMH will begin collecting fees one year before program implementation, in the first year of implementation, the final quarter of fiscal 2011. Therefore, one-on-one educational outreach may have to be significantly limited under the contract or general fund expenditures may be needed to capitalize the program.

Legislative Services advises that in the absence of general funds, a viable program that does not include one-on-one health care provider education may be accomplished through seminars, mailings, and web site postings which significantly reduces program staffing needs and associated costs. However, a viable program that includes such one-on-one outreach in the workplace is likely to cost almost \$1 million on an annual basis.

The bill has no effect on expenditures in fiscal 2010 since it does not authorize Evidence-Based Prescriber Education and Outreach Program activity before April 1, 2011. However, in fiscal 2011 special fund expenditures increase by \$277,052 to begin implementing the program in the final quarter. This estimate assumes that the Board of Physicians and Board of Pharmacy contract with the University of Maryland School of Pharmacy to take sole responsibility for program development and administration. The estimate is mostly driven by the pharmacists necessary to provide one-on-one outreach to health care providers throughout the State; thus, the University of Maryland School of Pharmacy must hire eight full-time equivalent staff to conduct comparative effectiveness analysis, provide health care professionals with information and education regarding the comparative effectiveness of prescription drugs, and support the administrative operations of the program. The estimate includes salaries for:

- one assistant professor (90% time) to gather, analyze, and make decisions regarding comparative effectiveness studies and to develop educational materials;
- three full-time pharmacists to assist the assistant professor in the analysis, material development, and provide one-on-one outreach and education to health care providers;
- six part-time pharmacists who only provide one-on-one health provider outreach and education; and
- one administrative assistant to support the administrative operations of the program.

The estimate also includes fringe benefits, one-time start-up costs, and ongoing operating expenses. Since the fiscal 2011 estimate represents just three months of operation given the April 1, 2011 start date, fiscal 2012 is also shown.

	<u>FY 2011</u>	<u>FY 2012</u>
Positions	5	5
Part-time Positions	6	6
Salaries and Fringe Benefits	\$223,268	\$908,155
Operating Expenses	7,244	29,265
Start-up Costs	46,540	0
Total Expenditures	\$277,052	\$937,420

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

Additional Comments: The University of Maryland advises that the program has the potential to reduce costs for other State programs by optimizing health outcomes and reducing drug costs. The university cites in support a study in the *New England Journal of Medicine* that indicated a \$2 savings can be realized for every \$1 expended on such a program. Legislative Services cannot reliably estimate the extent of any such cost savings the State may realize.

Additional Information

Prior Introductions: None.

Cross File: SB 708 (Senator Pugh, *et al.*) - Finance.

Information Source(s): Department of Health and Mental Hygiene, University System of Maryland, Department of Legislative Services

Fiscal Note History: First Reader - February 25, 2009
ncs/mcr Revised - Correction - March 8, 2009

Analysis by: Sarah K. Volker

Direct Inquiries to:
(410) 946-5510
(301) 970-5510