SB 708

Department of Legislative Services

Maryland General Assembly
2013 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 708 (Senator Madaleno, *et al.*)

Finance Economic Matters and Health and Government Operations

Tobacco-Related Disease Products Research, Development, and Commercialization Program

This bill establishes the Tobacco-Related Disease Products Research, Development, and Commercialization Program and Fund. The Maryland Biotechnology Center in the Department of Business and Economic Development (DBED) must administer the fund.

The bill requires the Governor to provide $1.0 million annually, beginning in fiscal 2015, for the fund – from the appropriations made annually from the Cigarette Restitution Fund (CRF) to the Maryland Medical Assistance Program (Medicaid).

The bill takes effect July 1, 2013, and terminates June 30, 2018.

Fiscal Summary

State Effect: General fund expenditures increase by $1.0 million annually from FY 2014 through 2018. In FY 2014, general funds are used to capitalize the new special fund; thus in FY 2014, special fund revenues and expenditures also increase by $1.0 million. In FY 2015 through 2018, general funds must provide support to Medicaid that would otherwise be provided by CRF special funds. As those CRF monies are shifted to capitalize the new fund for four years, total special fund revenues and expenditures do not change in those years. Special fund revenues (and expenditures) may increase due to grantee repayment to the State through royalties on sales of grant-developed products; however, any such impact is limited because the program and fund terminate after FY 2018. **This bill establishes a mandated appropriation beginning in FY 2015**.

(in dollars)	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
SF Revenue	$1,000,000	$0	$0	$0	$0
GF Expenditure	$1,000,000	$1,000,000	$1,000,000	$1,000,000	$1,000,000
SF Expenditure	$1,000,000	$0	$0	$0	$0
Net Effect	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)

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

Local Effect: None.

Small Business Effect: Potential meaningful for any small businesses that receive grants under the program.

Analysis

Bill Summary: The purpose of the program is to promote the research, development, and commercialization of innovative products and technologies that address tobacco-related diseases. In consultation with the Department of Health and Mental Hygiene (DHMH), the Maryland Biotechnology Center in DBED must award grants to applicants on a competitive basis, with priority given to the following criteria: (1) the technical and scientific merit of the applicant's proposal and its potential ability to address the unmet medical needs of the citizens of Maryland, including the needs of smokers, former smokers, and nonsmokers exposed to secondhand smoke; (2) the degree of the association between cigarette smoking and the disease being addressed by the applicant's proposal; (3) as specified by the bill, the amount of time the proposal is likely to take to result in a late-stage clinical trial or marketed product; (4) the applicant's track record in bringing products to market; (5) the applicant's track record in leveraging other funding sources, including private capital; and (6) the potential for the creation of new jobs in the State that can be sustained without continued State funding, including manufacturing jobs.

Grant awards must be made in the following amounts: $200,000 for a single company or $300,000 for a company collaborating with a nonprofit medical research institute or care facility in the State. An applicant may not receive more than one grant award per fiscal year.

Grant award recipients that use money from the fund to develop or improve a product or service, resulting in a marketed product or service, must pay to the State a royalty of 3% of the net sales of the product or service (not to exceed 300% of the amount of the grant received under the program). Royalties must be deposited into the fund and used to provide future awards under the program.

The purpose of the fund (a special, nonlapsing fund) is to provide grant money to support the purposes of the program. The fund must be used to cover the costs of the program – including any grants awarded to eligible recipients – and consists of money appropriated in the State budget to the fund including money appropriated from CRF, royalties received under the bill, investment earnings of the fund, and any other money from any other source accepted for the benefit of the fund. Interest earnings of the fund accrue to the fund rather than to the State's general fund. Fund expenditures may be made only in accordance with the State budget.

DBED may adopt regulations to implement the bill.

Current Law/Background:

CRF Program and Medicaid

The CRF Program receives a majority of its funding from payments made under the Master Settlement Agreement, through which tobacco manufacturers will pay approximately $206 billion (over a period of years) to 46 states, five territories, and the District of Columbia. CRF is required to be appropriated to eight priorities related to health and tobacco. At least 30% of CRF appropriations must be for Medicaid; in practice, however, significantly more than the mandated amount has been directed to the Medicaid program (to substitute for general funds that would otherwise be required).

In-state Development of Devices for the Treatment of Cancer

The 2012 *Joint Chairmen's Report* included language requiring DHMH to, in conjunction with DBED, submit a report on research and development collaborations between Maryland companies and Maryland academic researchers that accelerate the development of devices, diagnostics, and therapeutics for improving cancer outcomes. The resulting report is summarized below.

Maryland is home to more than 500 bioscience companies, including 91 actively engaged in research and development of products related to cancer. Since the inception of the Maryland Industrial Partnerships (MIPS) program in 1987, the State has committed itself to the development of collaborative relationships between companies and universities; in fact, The Johns Hopkins University and the University System of Maryland (USM) are currently involved in nearly 30 cancer-related research projects with Maryland-based companies. Though some of these projects are funded through CRF, the vast majority are not. Cumulatively, these projects represent nearly $10 million in funding.

Several other programs also support research and development of cancer treatment devices in Maryland. These include the following:

- *Maryland Biotechnology Center Translational Research Award*: Funding supports collaborations between private companies in the State and academic research programs.

- *Biotechnology Investment Incentive Tax Credit Program*: Program provides income tax credits equal to 50% of an eligible investment for investors in qualified Maryland biotechnology companies. Total credit certificates issued in a fiscal year may not exceed the budgeted amount.

- *InvestMaryland*: Through a premium insurance tax credit auction sale (whereby future tax credits are sold to insurance companies at a discount) the State raised $84 million in venture capital funding to invest in early-stage technologies in areas including life sciences, software, communications, and cyber security.

- *MIPS*: Program accelerates the commercialization of technology in Maryland by funding collaborative research and development projects between companies and USM faculty.

State Fiscal Effect: In the first year of the program, which is limited to five years under the bill, it is assumed that the new special fund is capitalized with general funds in the same amount as mandated to be provided from CRF special funds in the next four years. Thus, in fiscal 2014, general fund expenditures (and special fund revenues and expenditures) increase by $1.0 million. However, in fiscal 2015 through 2018, CRF special funds that would otherwise support the State's Medicaid program are redirected to the new special fund. Thus, the additional CRF special fund mandates result in less special funding for Medicaid. Accordingly, the Department of Legislative Services (DLS) advises that general fund expenditures likewise increase by $1.0 million annually from fiscal 2014 through 2018 due to the need to support Medicaid with general funds rather than the support that otherwise would have been provided by CRF special funds.

Although special fund revenues (and expenditures) may increase – to the extent that grantees repay funds to the State through royalties on sales of grant-developed products, any such impact cannot be reliably estimated.

DBED advises that, based on the department's experience with similar funding programs, one additional full-time employee is needed to implement the bill. DLS concurs that additional staff is needed to develop regulations and procedures, solicit and review program applications, collect any royalties received by the State, and provide general administrative support. However, because the program is limited to five years, contractual, rather than permanent, staffing is likely. Any such staffing and other administrative costs are included in estimated special fund expenditures but reduce the amount of grant funds that may be awarded.

Additional Comments: As noted above, the bill requires royalties to be deposited into the fund and used for future awards. However, it is unclear to what extent any royalties will be collected and deposited into the fund before the bill's July 1, 2018 termination date. DLS advises that, if the mandated appropriation (rather than the bill) were to terminate after five years, royalties could be collected and used to fund the program in future years.

Additional Information

Prior Introductions: None.

Cross File: HB 948 (Delegate Reznik, *et al.*) - Economic Matters and Health and Government Operations.

Information Source(s): Department of Business and Economic Development, Department of Budget and Management, Department of Health and Mental Hygiene, University of Maryland Medical System, Department of Legislative Services

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