# Department of Legislative Services

Maryland General Assembly
2012 Session

## FISCAL AND POLICY NOTE

House Bill 1167 (Delegate Reznik, *et al.*)
Health and Government Operations

**Cigarette Restitution Fund - Lung Cancer Screening and Biotechnology**

This bill establishes (1) a Lung Cancer Medical Committee in the Department of Health and Mental Hygiene (DHMH); and (2) a Lung Cancer Screening Component and a Lung Cancer Biotechnology Research and Development Component in the Cancer Prevention, Education, Screening, and Treatment Program administered under the Cigarette Restitution Fund (CRF) Program. The bill requires the Governor to include an appropriation in the annual budget, beginning in fiscal 2014, of at least $5.0 million for the Lung Cancer Screening Component and at least $2.5 million for the Lung Cancer Biotechnology Research and Development Component. In addition, the bill specifies that, in awarding Academic Health Center Research Grants, priority must be given to academic health centers that have contracts (with Maryland companies) that are reasonably likely to lead to commercialization of products in Maryland within three to five years after the grant is awarded. DHMH must adopt specified regulations to implement the bill.

## Fiscal Summary

**State Effect:** Expenditures are not affected in FY 2013. General fund expenditures increase by $7.5 million annually beginning in FY 2014 due to the use of general funds to provide support that would otherwise be provided by CRF special funds to the Maryland Medical Assistance Program (Medicaid). It is assumed that funds appropriated for the new components under the bill may be used to cover administration costs, which are expected to be significant. State revenues may increase in future years to the extent that grantees repay funds to the State through royalties on sales of grant-developed products. **This bill establishes mandated appropriations beginning in FY 2014.**

| ($ in millions) | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---|---|---|---|---|
| Revenues | $0 | $0 | $0 | $0 | $0 |
| GF Expenditure | 0 | 7.5 | 7.5 | 7.5 | 7.5 |
| Net Effect | $.0 | ($7.5) | ($7.5) | ($7.5) | ($7.5) |

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

**Local Effect:** Assuming that physicians can apply directly to DHMH (rather than to local health departments) for screening vouchers under the Lung Cancer Screening Component, the bill does not directly affect local government finances or operations.

**Small Business Effect:** Potential meaningful for any small businesses that receive grants under the Lung Cancer Biotechnology Research and Development Component and for small business lung cancer screening test providers that may perform additional screening due to the availability of vouchers.

## Analysis

**Bill Summary:** The Lung Cancer Medical Committee consists of five members with specified expertise. A member of the committee may not receive compensation as a member of the committee but is entitled to reimbursement for expenses. The committee must determine which tests and test providers are eligible for reimbursement under the Lung Cancer Screening Component.

The purpose of the Lung Cancer Screening Component is to provide reimbursement in the form of vouchers for lung cancer screening. DHMH may make eligible reimbursement vouchers (on application to the department by State-licensed physicians) for certain types of testing, as specified by the bill. A physician receiving a voucher must refer a patient to an eligible test provider, who must accept the voucher as compensation for providing lung cancer screening testing for the patient. DHMH is required to establish the reimbursement rates for vouchers. Test providers must apply to DHMH for approval to be eligible to participate.

The purpose of the Lung Cancer Biotechnology Research and Development Component is to provide funding in the form of grants for research and development of therapeutic, diagnostic, and medical devices that are useful in addressing lung cancer. DHMH is required to select and administer grant awards based on the recommendations of the Life Sciences Advisory Board in the Department of Business and Economic Development (DBED). Priority for grants must be given to (1) applicants who can demonstrate that the funding will lead to the creation of jobs in Maryland that can be sustained without perpetual government funding; (2) medical device and diagnostic projects that can be commercialized within 12 months after the end of the grant period; and (3) therapeutic projects that can be commercialized within 36 months after the end of the grant period.

Before receiving a grant, an applicant must submit a cancer research plan as specified by the bill, as well as enter into a memorandum of understanding with DHMH, DBED, and the Maryland Technology Development Corporation. The memorandum of understanding must (1) establish the scope of the State's ownership or other financial

interest in the commercialization and other benefits of the results, products, inventions, and discoveries of the grant-funded treatment technology; (2) establish a plan for expediting the translation of treatment technology into production for public use; (3) to the extent consistent with federal and State law, reflect the intellectual property policies of the program; and (4) require the grantee to repay to the State 150% of the value of the grant through royalties on sales of lung cancer products developed with the grant.

**Current Law/Background:** 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.

One of CRF's programs is the Cancer Prevention, Education, Screening, and Treatment Program, which funds community-based programs that prevent, detect, and treat cancer – including grants to academic health centers for cancer research. For fiscal 2013 and each following year, the Governor is required to include at least $13.0 million in the annual budget in appropriations for Statewide Academic Health Center Cancer Research Grants, to be distributed according to historical allocations between the centers.

The mission of the Cancer Prevention, Education, Screening and Treatment Program is to reduce the burden of cancer (including cancers related to tobacco use) among Maryland residents by reducing overall cancer mortality in the State. At least 30% of CRF appropriations must be for the Medicaid programs. 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).

**State Revenues:** State revenues may increase in future years to the extent that grantees repay funds to the State through royalties on sales of grant-developed products.

**State Expenditures:** DHMH advises that 12 additional full-time employees are needed – at a cost of more than $600,000 annually – to implement the bill. Specifically, the department advises that it must hire:

- one full-time program administrator to develop and oversee the two new components, develop an application for providers and a voucher format, develop a request for proposals for the grant component, and monitor grantees;
- one full-time nurse program consultant to staff the committee, oversee the clinical components of the screening program, and review invoices;
- two full-time information technology (IT) programmer analysts to operate the billing software, troubleshoot software problems, and maintain a database of participating providers;

- four full-time fiscal accounts clerks to receive vouchers, enter information into the billing system, and process payments; and
- four full-time office clerks to process provider paperwork, mail vouchers, and provide customer service.

In addition, DHMH advises that it must establish a vendor contract for an online bill paying system at an initial cost of approximately $500,000 (and $294,000 annually thereafter for system maintenance and updates). Furthermore, DBED advises that its costs (associated with entering into memoranda of understanding) under the bill may not be absorbable, depending on the nature of regulations established for the process.

Legislative Services concurs that significant staffing and start-up costs are necessary to implement the bill. However, Legislative Services advises that fewer new employees than are anticipated by DHMH may be needed to implement the bill. For example, one full-time administrator can likely fulfill the duties anticipated by DHMH for the full-time administrator and the full-time nurse program consultant. In addition, fewer clerical staff may be needed, depending on program participation. It may also be possible to phase in clerical staff, depending on growth in program participation. Nevertheless, Legislative Services advises that significant staffing and start-up costs are needed to implement the bill.

For purposes of this estimate, Legislative Services assumes that funds appropriated for the new components under the bill may be used to cover costs associated with administering those components.

CRF special funds that are not spent on specific statutory mandates are used to support the State's Medicaid program. Thus, additional CFR special fund mandates result in less special funding for that program. Accordingly, Legislative Services advises that general fund expenditures are not affected in fiscal 2013 but increase by $7.5 million annually beginning in fiscal 2014 due to the need to expend general funds to provide support for Medicaid that would otherwise be provided by CRF special funds.

Any effect on the University of Maryland Medical System (UMMS) related to the bill's changes regarding the allocation of Academic Health Center Research Grants cannot be reliably estimated at this time. UMMS did not respond to requests for information for this fiscal and policy note.

To the extent lung cancer screening reduces morbidity from the disease, the health care system (including the Medicaid program) may realize savings. Any such impact cannot be reliably quantified.

## Additional Information

**Prior Introductions:** None.

**Cross File:** None.

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

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