HB 216

Department of Legislative Services

Maryland General Assembly
2008 Session

FISCAL AND POLICY NOTE
Revised

House Bill 216 (Chair, Health and Government Operations Committee)
(By Request – Departmental – Health and Mental Hygiene)

Health and Government Operations Finance

Hereditary and Congenital Disorders - Newborn Screening

This departmental bill codifies a statewide system for screening all newborn infants in the State for hereditary and congenital disorders. In addition, the Department of Health and Mental Hygiene is required to study whether a coordinated statewide system for screening newborn infants in the State for hereditary and congenital disorders should be applied to all newborn infants in the State. DHMH must report on the study's conclusions to specified legislative committees by December 1, 2008.

The bill takes effect June 1, 2009, although provisions directing program implementation take effect January 1, 2009.

Fiscal Summary

State Effect: General fund revenues could increase by $1,132,200 in FY 2009 due to increased fees required to cover screening costs and an increase in the number of screening fees collected. This estimate also reflects the January 1, 2009 program implementation date. Future years reflect annualization. General fund expenditures due to program expansion could increase by $1,132,100 in FY 2009. Future years reflect annualization and inflation. DHMH should be able to conduct the required study with existing resources.

(in dollars)	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
GF Revenue	$1,132,200	$2,264,400	$2,264,400	$2,264,400	$2,264,400
GF Expenditure	1,132,100	1,315,300	1,346,500	1,004,100	1,038,000
Net Effect	$100	$949,100	$917,900	$1,260,300	$1,226,400

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

Local Effect: None.

Small Business Effect: The Department of Health and Mental Hygiene has determined that this bill has minimal or no impact on small business (attached). Legislative Services concurs with this assessment. (The attached assessment does not reflect amendments to the bill.)

Analysis

Bill Summary: Parents or guardians have the option to withdraw a newborn from screening.

The bill specifies that the DHMH Public Health Laboratory is the *only* laboratory authorized to perform the screening tests. However, the Secretary, with the approval of the State Advisory Council on Hereditary and Congenital Disorders, may contract or delegate the screening program to another entity. In addition, any necessary postscreening or diagnostic tests may be performed by another entity. Any such entity has to obtain a license issued by the Secretary and meet all standards and requirements for a laboratory to perform tests on newborn infants for hereditary and congenital disorders that are established by the Secretary.

The system for newborn screening has to include laboratory testing and reporting of test results, as well as follow-up activities to facilitate the rapid identification and treatment of an affected child.

DHMH, in consultation with the State Advisory Council on Hereditary and Congenital Disorders must:

- establish protocols for a health care provider to obtain and deliver test specimens to DHMH's Public Health Laboratory;
- determine the screening tests that the laboratory is required to perform;
- maintain a coordinated statewide system for newborn screening that includes (1) communicating the results of screening tests to the appropriate health care provider of the infant; (2) locating infants with abnormal test results; and (3) sharing screening information; and
- adopt regulations that set standards and requirements for screening including (1) performing screening tests; (2) coordinating the reporting, follow up, and treatment activities; and (3) establishing fees for screening that do not exceed the

amount sufficient to cover the administrative, laboratory, and follow-up costs necessary to perform the screening tests.

Current Law: Participation in a hereditary and congenital disorders program is voluntary, and all information obtained about any individual in such a program is kept confidential. DHMH adopts rules, regulations, and standards for the program in consultation with • the public; • subject matter experts; and • the State Advisory Council on Hereditary and Congenital Disorders.

The State Advisory Council on Hereditary and Congenital Disorders:

- gathers and gives out information to further the public's understanding of hereditary and congenital disorders;
- reevaluates the need for and the effectiveness of State hereditary and congenital disorders programs;
- makes any necessary recommendation to end any unjustified discrimination that might result from identifying an individual as a carrier of a hereditary disorder;
- advises the Secretary on the need for rules, regulations, and standards for the detection and management of hereditary and congenital disorders;
- participates in the development of the rules and regulations adopted by DHMH; and
- assists DHMH in prioritizing its efforts.

Background: DHMH's newborn screening program has provided screening for hereditary and congenital disorders for 36 of the last 40 years. However, over the past four years some hospitals have contracted with an out-of-state provider for screening services. Of the 74,000 babies born annually in Maryland, 22,200 babies are currently being screened outside the DHMH laboratory system.

State Revenues: DHMH currently screens 51,800 babies annually for a fee of $42 per baby and does not charge a fee for standard follow-up screenings. However, under the bill, DHMH advises that it plans to charge $60 per baby screening and a $10 fee for each standard follow-up screening for a total of $70 per baby. DHMH advises that the $42 fee was established when it screened for nine disorders. The number of screened disorders has increased to 35, making the $42 fee insufficient to cover current screening costs. However, given the bill's mandate that fees for newborn screening *not* exceed an amount sufficient to cover costs associated with performing screenings, Legislative Services advises that, at most, $50 per baby screening and a $10 follow-up fee would be needed to cover both current and expanded screening program costs. While Legislative Services agrees that the $42 screening fee does not cover current program costs, the revenue generated from increasing the fee to $70 would significantly exceed the amount necessary for cost recovery.

Under the bill, 22,200 additional babies would be screened by the DHMH laboratory, bringing the total number of babies screened to 74,000 annually, assuming no change in the birth rate. General fund revenues due to the fee increase and the additional 22,200 screenings are estimated to be $1,132,200 in fiscal 2009, which reflects the program's January 1, 2009 effective date and a total fee of $60 per baby. In future years, general fund revenues would increase by $2,264,400. Thus, total program revenues (existing and new) should satisfy with the bill's cost-recovery provision by offsetting total program expenditures, but not exceeding them.

State Expenditures: General fund expenditures could increase by an estimated $1,132,071 in fiscal 2009, which accounts for the program's January 1, 2009 effective date. This estimate reflects the cost of hiring seven full-time employees (three lab scientists, one office secretary, one data programmer, one office clerk, and one nursing program consultant) to handle the 22,200 extra screenings. The newborn screening program currently operates with 20 employees. The estimate also reflects one-time purchasing costs for additional equipment (including a mass spectrometer at $375,000) necessary to handle the increased caseload, and new software necessary to meet the bill's requirements for statewide screening coordination and information dissemination. The estimate includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Positions	7
Salaries and Fringe Benefits	$197,644
Operating Expenses	256,817
Start-up Costs	677,610
Total FY 2009 State Expenditures	**$1,132,071**

Future year expenditures reflect • full salaries with 4.4% annual increase and 3% employee turnover; and • 2% annual increases in ongoing operating expenses.

In future years, DHMH may need to replace the two mass spectrometers currently being used for the program due to general equipment wear and the increased caseload. The cost of each mass spectrometer is $375,000, the purchase of which is reflected in fiscal 2010 and 2011. DHMH should be able to conduct the required study on the statewide system with existing resources.

Additional Comments: To the extent that hospital rates increase to account for the increased costs of newborn screening, Medicaid expenditures (50% general funds, 50% federal funds) could increase. Medicaid's share of total hospital revenues is approximately 18%. Commercial insurance premiums could also increase if hospital rates were increased. Commercial insurance comprises 37% of total hospital revenues. Any increase to the Medicaid program or commercial insurance cannot be reliably estimated at this time but would likely be minimal.

Additional Information

Prior Introductions: None.

Cross File: None.

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

Fiscal Note History:	First Reader - February 4, 2008
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