

Department of Planning and Budget 2005 Fiscal Impact Statement

1. Bill Number SB 1184E

House of Origin ☐ Introduced ☐ Substitute ☒ Engrossed
Second House ☐ In Committee ☐ Substitute ☐ Enrolled

2. Patron: Puller.

3. Committee: Education and Health.

4. Title: Newborn Screening.

5. Summary/Purpose: This bill broadens the Commonwealth's newborn screening program for genetic disorders to include approximately 30 or more conditions that cause mental retardation, serious disability, or death if left untreated. The screening tests to be included in Virginia's panel of disorders will be consistent with, but not necessarily identical to, the uniform condition panel recommended by the American College of Medical Genetics in its 2004 report, Newborn Screening: Toward a Uniform Screening Panel and System. Upon the issuance of a panel of recommended tests by the federal Department of Health and Human Services, Virginia's testing program will be consistent with, but not necessarily identical to, the federal guidance document. The Board of Health's regulations must include a list of conditions for which newborn screening tests are conducted pursuant to § 32.1-65, follow-up and referral protocols and necessary provisions to implement the newborn screening services, and any services available to the infants and children through the Children with Special Health Care Needs Program. The mandate for the increased testing will become effective on March 1, 2006; however, the Board of Health is required to promulgate emergency regulations. The second enactment clause of a 2002 Act of the General Assembly that required certain funding is repealed in order to ensure the integrity of the law.

6. Fiscal Impact Estimates are: Preliminary.

6a. Expenditure Impact:

<i>Fiscal Year</i>	<i>GF</i>	<i>Dollars</i>	<i>NGF</i>	<i>Positions</i>
2004-05	\$ 0		\$0	0
2005-06	\$ 570,000		\$16,000 (Fund 0200 - Medicaid/Insurance)	2.50 FTE (Fund 0100)
2006-07	\$732,000		\$70,000 (Fund 0200 – Medicaid/Insurance)	2.50 FTE (Fund 0100)
2007-08	\$785,000		\$108,000 (Fund 0200 – Medicaid/Insurance)	2.50 FTE (Fund 0100)
2008-09	\$822,000		\$156,000 (Fund 0200 - Medicaid/Insurance)	2.50 FTE (Fund 0100)
2009-10	\$874,000		\$184,000 (Fund 0200 – Medicaid/Insurance)	2.50 FTE (Fund 0100)

6b. Revenue Impact:

<i>Fiscal Year</i>	<i>GF</i>	<i>Dollars</i>	<i>NGF</i>	<i>Positions</i>
2004-05		\$0	\$0	0
2005-06		\$0	\$ 16,000 (Fund 0200 - Medicaid/Insurance)	0
2006-07		\$0	\$70,000 (Fund 0200 – Medicaid/Insurance)	0
2007-08		\$0	\$108,000 (Fund 0200 - Medicaid/Insurance)	0
2008-09		\$0	\$156,000 (Fund 0200 – Medicaid/Insurance)	0
2009-10		\$0	\$184,000 (Fund 0200 - Medicaid/Insurance)	0

7. Budget amendment necessary: Yes. Item #313, State Health Services (4300300).

8. Fiscal implications: The expenditure and revenue estimates listed in Item 6 represent the impact to the Virginia Department of Health (VDH) of expanding the panel of newborn screening tests for metabolic disorders. The costs and revenues associated with the existing screening program are not included but detailed below.

On January 11, 2005, the Joint Commission on Health Care voted to recommend a budget amendment in the amount of \$935,500 in general fund to support the VDH portion of the newborn screening program. This budget amendment would cover the cost of the expansion for FY 2006 estimated to be \$586,000 and replace \$382,800 in funds historically received by VDH from the Newborn Screening users fee (paid by hospitals per infant blood sample submitted) through Division of Consolidated Laboratories (DCLS)/Department of General Services (DGS). The Joint Commission on Health Care voted to replace the VDH share of the Newborn Screening users fee with general fund to minimize the size of the fee increase that hospitals will pay to Division of Consolidated Laboratories as a result of expanding newborn screening services. Based on the assumption of funding VDH's costs from the general fund, the fee paid by the hospitals to DCLS is estimated to increase from \$32 to \$43.

The replacement general fund for \$382,800 would be a recurring annual expense.

Costs associated with laboratory testing, conducted by the Division of Consolidated Laboratory Services, and for any additional costs incurred by increased utilization of health services covered under Medicaid (Department of Medical Assistance Services) are not included in these estimates.

Several state sponsored studies and other published research have demonstrated that a comprehensive newborn screening program results in overall cost avoidance due to early detection, the subsequent need for less intensive treatment and institutionalization needs as well as containing education costs. For example, the State of Wisconsin has estimated that for every four dollars spent on newborn screening services, five dollars in costs are avoided.

The estimates costs for the expanded newborn screening program in FY 2006 are:

VDH Newborn Screening Services: Expanded Panel Only (Education, Follow-up, Diagnosis, Medical Management and Treatment Services)	Expenditure Subobject Code	Expanded Panel Expenses
Newborn Screening Services VDH Central Office Staff: 1.5 FTE Classified RN (1 FTE Classified RN @ \$50,000 base salary/\$14,000 fringe @28% and 0.5 FTE Classified RN @ \$22,500 base salary/\$6,300 fringe @ 28%); 0.66 Contract Support Staff (\$15,200 for 1380 hours @ \$11/hr (Staff will be responsible for conducting daily follow-up of abnormal results and administration of formula/food program)	1120	\$ 108,000
Professional Education Educate medical providers regarding expanded panel, development of materials for disorders on expanded panel; includes development of web-based training module for health care providers	1224	\$ 45,000
Information Technology Support Development/modifications to data reporting systems to report and track new disorders; outyear costs for system maintenance estimated at \$10,000 per year	1271	\$ 45,000
Contracts with Tertiary Centers Expert consultation on abnormal results and diagnostic testing, long-term medical management including dietary management; VDH currently contracts with Eastern Virginia Medical School, University of Virginia, and Virginia Commonwealth University for these services on the existing newborn screening panel	1234	\$ 218,000
Purchase of special metabolic formulas	1344	\$ 65,000*
Reimbursement for low protein modified foods	1362	\$ 20,000*
Care coordination services Adds 0.5 FTE to six regional Care Connection for Children centers for additional case management to maximize insurance coverage and facilitate family-to-family support; two of these half-time FTEs are with centers operated in the local health districts; the additional four centers are non-health department entities; budget estimates for full year will equal \$28,333 per 0.5 care coordinator	1234	\$ 85,000*
* = Partial year expenses		
TOTAL: VDH Newborn Screening Services (Expanded Panel Only) FY 2006		\$ 586,000

The Virginia Department of Health's existing newborn screening and follow-up services operate on an annual budget of \$741,252 comprised of \$382,807 in newborn screening test kit revenue (portion of fees collected from hospitals by the Division of Consolidated Laboratory Services), \$283,611 in federal Maternal and Child Health (Title V) block grant funding, \$54,834 in formula revenue (required 2% of gross family income contribution) and \$20,000 in general fund to support the costs of low protein modified foods.

Estimates for additional VDH central office staff are based on additional abnormal results requiring follow-up and additional staff needed to expand formula and food benefits administration. Staff costs are projected starting July 1, 2005 to allow for sufficient time for protocol development and medical provider training prior to March 1, 2006 screening implementation.

Professional education costs in subsequent years have been reduced to \$15,000 because the primary costs will be incurred during the first year of the expansion.

Information technology costs in subsequent years have been reduced to \$10,000 for maintenance. The initial cost in FY 2006 will be greater due to database redesign for the expanded battery of tests.

The contracts with the tertiary centers have been increased to better support the infrastructure of metabolic treatment centers. VDH is responsible for assuring that these services are available to Newborn Screening Services patients and their families. These centers employ physicians who provide expert consultation on all abnormal results, which may indicate a metabolic disorder. In addition, the metabolic treatment centers provide consultation for diagnostic testing and direct patient services for medical and nutritional long-term management. While some third party reimbursement is available for these services, it is not sufficient to cover the full cost. In addition, these centers provide services to the uninsured population (estimated to be 8%) at no cost to the patient. The estimates are based on a model developed by VDH for 25% of the expert physician salary and 50% of the registered dietician salary for each of the three metabolic treatment centers. The additional funding will cover the anticipated workload increases (projected to be about 50%). In FY 2008, this cost is projected to increase by 5% as the volume of metabolic disorder cases increases in each full year of implementation. No further increase is applied for these contract amounts through FY 2010.

Estimates provided for the formula and food portion are based on the current benefits prescribed in the Code of Virginia § 32.1-67 (families pay no more than 2% of gross income for metabolic formula and are eligible for \$2,000 reimbursement annually for the purchase of modified low-protein foods).

SB 1184 would allow VDH to prescribe treatment benefits through the regulatory process. Should VDH change treatment assistance to be congruent with the current Children with Special Health Care Needs Program, then the general fund required may be reduced as this program provides financial assistance for families at or below 300% Federal Poverty Level. Given that these regulations have not yet been developed in accordance with the Administrative Process Act (APA) and public input, estimates at this point remain based on the current program.

VDH estimates that an additional 18 new cases for the metabolic screening disorders and 28 cases of cystic fibrosis will be diagnosed each year. These are based on the best prevalence estimates available nationally through various sources.

Of the estimated 18 new metabolic disorder cases diagnosed each year, approximately 17 infants will need metabolic formula, and 10 infants will need modified low protein foods. Assumptions are for 75% participation in the metabolic formula and low protein food benefit with 3% inflation and 5% attrition projected annually. The annual per person formula cost is estimated to be \$5,550 based on prices obtained from suppliers. Formulas used to treat conditions under the expanded panel are different from those purchased in the current program, so historical costs are of limited value.

Third party recovery of some metabolic formula costs are expected through Women, Infants, and Children (WIC), Medicaid, and some private insurance. In Virginia, there is no mandate for insurers to cover costs of metabolic formulas and hence benefits differ among private insurance plans. In the current formula program 4% of recipients have WIC, 19% of recipients have Medicaid, and 44% of recipients have private insurance. In the current FY 2005 budget,

approximately 19% of VDH formula costs are budgeted to be recovered through third party reimbursement. This percentage has been increased annually up to 35% in FY 2010 due to anticipated increases in insurance coverage and benefits maximization through care coordination services not currently provided.

9. Specific agency or political subdivisions affected: Virginia Department of Health; Division of Consolidated Laboratory Services; Department of Medical Assistance Services.

10. Technical amendment necessary: None.

11. Other comments: The Joint Commission on Health Care (JCHC) conducted a study of expansion of the Newborn Screening Program pursuant to HJ 164 from the 2004 General Assembly Session. During its January 11, 2005 meeting, JCHC decided to recommend a budget amendment for \$953,500 to support the costs of expanded newborn screening, case management, treatment, and replacement of funds supporting the existing program that Division of Consolidated Laboratory Services will no longer provide to VDH from the Newborn Screening Users fee.

This bill is very similar to HB 1824 (Frederick). The differences in language between the two bills do not change the fiscal impact to VDH.

SB 1184 (Puller) is identical to HB 2511.

HB 2011 (Armstrong) introduced January 12, 2005 would mandate that private insurers cover metabolic formulas. If passed, this would lessen some of the costs incurred by VDH for formula benefits provided to privately insured persons. In 2004, the Commission on Mandated Benefits unanimously voted against a similar bill (HB 1216) from the 2004 General Assembly Session. Instead, the Commission recommended writing a letter to recommend funds to expand the VDH metabolic formula program.

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Cc: Secretary of Health and Human Resources