

Department of Planning and Budget 2015 Fiscal Impact Statement

1. Bill Number: SB835

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

2. Patron: Edwards

3. Committee: Education and Health

4. Title: Newborn screening; Krabbe disease.

5. Summary: Requires the screening tests conducted on every infant born in the Commonwealth to include a screening test for Krabbe disease and other lysosomal storage disorders.

6. Budget Amendment Necessary: Yes

7. Fiscal Impact Estimates: Fiscal impact estimates are preliminary. See Item 8.

7a. Expenditure Impact:

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2015	0	NGF
2016	\$2,396,000	NGF
2017	\$468,000	NGF
2018	\$468,000	NGF
2019	\$468,000	NGF

7b. Revenue Impact:

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2015	0	NGF
2016	\$1,110,667	NGF
2017	\$1,110,667	NGF
2018	\$1,110,667	NGF
2019	\$468,000	NGF

8. Fiscal Implications: Screening tests for various disorders are required for every infant born in the Commonwealth. Medical providers are responsible for ensuring required tests are performed by the Department of General Services (DSG) Division of Consolidated Laboratory Services (DCLS) or another laboratory the Virginia Department of Health has contracted to provide testing services. The Department of Health coordinates follow-up activities for newborns identified as at risk for tested disorders.

Funding for DCLS lab testing and the Department of Health's coordination and education services are recovered from a fee charged to medical providers for each screening test conducted by DCLS. The current fee is \$78 per infant.

There should be no fiscal impact to the Department of Health and any potential impact on the current workload can be absorbed.

Department of General Services:

According to DGS, DCLS is expected to incur an initial cost of \$2,396,000 the first year of testing, of which \$1,928,000 is associated with one-time costs and \$468,000 will be ongoing. Newborn screening tests are typically completed within 24 hours. Given the additional volume of tests needed to screen for Krabbe disease and other lysosomal storage disorders, additional staffing and equipment would be needed to maintain the 24 hour turnaround timeframe.

One-time costs include the following additional equipment and modifications: three mass spectrometers at a cost of \$500,000 each, two liquid handlers costing \$74,000 each, two centrifuges at \$10,000 each, \$80,000 in nitrogen generation equipment, \$100,000 for Lab Information Management System expenses, and \$80,000 for lab space modifications.

Annual ongoing costs of \$468,000 include three additional scientists for a total of \$210,000, \$148,000 for equipment maintenance, \$110,000 for reagents.

An increase to the current DCLS testing fee of approximately \$10 would be expected to recover the initial and ongoing costs DCLS over a period of three years. After three years, the rate is expected to decrease because the initial one-time equipment costs should be paid off. DCLS costs and revenue estimates are shown above in Item 7.

Department of Medical Assistance Services:

Adding Krabbe Disease and lysosomal storage disorders to the existing newborn screening panel would have some fiscal impact on the Department of Medical Assistance Services (DMAS), as the agency could experience follow-up screening and additional treatment costs. The estimated total cost is likely to be less than \$50,000 annually (total funds) based on available data and assumptions related to the impacted population. However, the agency does not have a clear estimate as to a cost for follow-up testing at this time.

Between state fiscal years 2011 and 2014, DMAS provided coverage for a primary diagnosis of Leukodystrophy (a broader category that includes Krabbe Disease) for an average of nine members a year at an annual cost of \$6,828 under the fee-for-service system. In addition, coverage was provided to an average of 12 members a year under a managed care plan. Based on an assumed start date of July 1st, 2015, an expected incidence rate for Krabbe Disease and lysosomal storage disorders that is equal to that seen in the general population, and the assumption that all recipients of these services would not be otherwise diagnosed, DMAS estimates that three additional recipients per year would receive treatment services related to the diagnosis of these conditions. Using an average cost equal to that seen over the

past four state fiscal years and an expected life expectancy of two years, this would increase costs by \$19,343 in FY 2016, approximately half of which would be supported with general fund dollars. It is assumed that costs would increase by increase by 100 percent the following year as those diagnosed the previous year would still receive treatment in addition to those newly diagnosed.

Adding conditions to the newborn screening panel may require the agency to cover follow-up testing to eliminate false positive results that will inevitably occur. DMAS estimates that additional testing may be needed for approximately 200 members each year. However a specific cost cannot be determined at this time. The fiscal impact statement will be revised when estimates are available.

9. Specific Agency or Political Subdivisions Affected: Department of General Services, Department of Health, Department of Medical Assistance Services

10. Technical Amendment Necessary: No

11. Other Comments: This bill is identical to HB1420.

Date: 1/27/2015

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