Department of Planning and Budget
2020 Fiscal Impact Statement

1. **Bill Number:** HB97

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

2. **Patron:** Miyares

3. **Committee:** Health, Welfare and Institutions

4. **Title:** Newborn screening; Krabbe disease and other lysosomal storage disorders.

5. **Summary:** Requires that newborn screening tests required to be performed on every infant born in the Commonwealth shall include screening for Krabbe disease and other lysosomal storage disorders for which a screening test is available.

6. **Budget Amendment Necessary**: Yes, item 76 and item 301.

7. **Fiscal Impact Estimates:** Preliminary, see item #8.

7a. Expenditure Impact:

Fiscal Year	*Dollars*	*Positions*	*Fund*
2021	$3,551,838	12	General
2022	$3,379,838	12	Nongeneral
2023	$3,379,838	12	Nongeneral
2024	$3,379,838	12	Nongeneral
2025	$3,379,838	12	Nongeneral
2026	$3,379,838	12	Nongeneral
2027	$3,379,838	12	Nongeneral
2028	$3,379,838	12	Nongeneral
2029	$3,379,838	12	Nongeneral

7b. Revenue Impact:

Fiscal Year	*Dollars*	*Fund*
2021	$0	
2022	$3,379,838	Nongeneral
2023	$3,379,838	Nongeneral
2024	$3,379,838	Nongeneral
2025	$3,379,838	Nongeneral
2026	$3,379,838	Nongeneral
2027	$3,379,838	Nongeneral
2028	$3,379,838	Nongeneral
2029	$3,379,838	Nongeneral

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). The Department of Health coordinates follow-up activities for newborns identified as at-risk for tested disorders. The bill requires that these screening tests shall include screening for Krabbe disease and all other lysosomal storage disorders (LSD) for which a screening test is available. This could include four other disorders in addition to Krabbe: Fabry, Gaucher, Mucopolysaccharidosis Type II (MPS II), and Neimann-Pick A/B. Additionally, the processes for the implementation of two LSDs, Pompe and Mucopolysaccharidosis Type I (MPS-1), have already begun and the testing methodology will have to be modified to accommodate the expanded panel.

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. DCLS transfers funding to support the work performed by VDH as required by the MOU. The current fee is $138 per infant.

Department of General Services: The Division of Consolidated Labs is expected to incur an initial cost of $3,586,976 from the general fund in FY2021 for testing (purchase of reagent kits), software modifications, and staffing to handle the increase in workload. This new testing requirement would require major modifications to the two software applications (one for instrument and quality control management and the other for sample tracking and reporting) employed by Newborn Screening. These services will require the procurement of both external and internal IT resources. These one-time costs are estimated at $177,000 for software modifications. There also would be $3,409,976 in ongoing costs supported by fee revenue. This impact statement assumes that general fund support will be needed in the first year for start-up and initial implementation costs for these tests until fee revenue is realized.

DGS has indicated that the current fee level of $138 would not generate enough revenue to cover the costs of current operations and the testing required by this bill. Based on the DGS estimates of approximately 100,000 screenings per year, the additional screening costs for adding Krabbe, Gaucher, Fabry and Niemann-Pick A/B would raise the newborn screening fee by an estimated $34.15 above the current fee. The resulting new NBS test cost would be approximately $172.15 per infant; however, it should be noted that these estimates do not include estimates for the consumer price index adjusted costs at the time of implementation or annual population increases.

Newborn screening tests are typically completed within 24 hours of birth. 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. DGS has estimated it would need 10 positions to handle the increase in workload. Four laboratory personnel would be needed for the initial screening, including: 1) Two bench scientists to perform the testing at an annual rate of $70,000 for each scientist; 2) one senior scientist to review and approve results and assist in troubleshooting at an annual rate of $79,000; and, 3) one operations Manager to support the expansion of the Newborn Screening laboratory at an annual rate of $114,000.

Due to the need to confirm and further refine all abnormal initial mass spectrometry LSD results, additional molecular testing will be required whenever a sample is out of the normal

range on the initial screen. DGS has estimated this would require an additional six positions. The molecular confirmatory testing itself will require two scientists to perform the sequencing analyses at an annual rate of $70,000 per scientist, and one molecular senior scientist is needed to review and approve results and assist in troubleshooting issues at an annual rate of $79,000. Due the extensive interpretative DNA variant analysis required when performing DNA sequencing, a senior scientist with a specialty in Bioinformatics is needed at an annual rate of $100,000. Since testing for all newborn screening disorders occurs simultaneously, so that results can be reported out as quickly as possible (24-48 hours), two additional staff are required for the new testing; a lead scientist at an annual rate of $114,000 and a data scientist at an annual rate of $70,000.

It is assumed that implementation will take one year to complete, however, additional general fund dollars may be needed in the second year depending on the extent to which DGS can complete its software modifications. Cost estimates for DGS are included in the tables above.

Department of Health: To meet the provisions of the bill, VDH has estimated it would need a follow-up nurse at an annual rate of $105,069. The agency also would need a nurse educator at an annual rate of $105,069. Due to the rapid expansion of the Virginia Newborn Screening panel, a dedicated nurse educator is required to educate stakeholders including nurses, pediatricians, neonatologists, obstetricians/gynecologists and parents throughout the Commonwealth. There also would be a one-time cost of $5,000 to contract with an outside vendor to add education content to the program's existing web-based education module (newbornscreeningeducation.org). Total start-up costs in FY2021 would be $215,138 from the general fund, and $210,138 from fee revenue annually thereafter to ensure timely follow-up of infants once implementation occurs. However, depending on how long it takes to implement the provisions of the bill, general fund costs could be needed until fee revenue is realized. Cost estimates for VDH are included in the tables above.

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 agency does not have a clear estimate as to a cost for follow-up testing at this time.

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 and the Virginia Department of Health.

10. **Technical Amendment Necessary:** No.

11. Other Comments: None.