

Department of Planning and Budget 2018 Fiscal Impact Statement

1. Bill Number: SB449

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

2. Patron: Chafin

3. Committee: Education and Health

4. Title: Newborn screening; lysosomal storage disorders.

5. Summary: Clarifies that newborn screening tests performed on infants born in the Commonwealth shall include screening for Pompe disease, mucopolysaccharidosis type 1 (MPS-1), and other lysosomal storage disorders for which a screening test approved by the U.S. Food and Drug Administration exists. The bill contains technical amendments.

6. Budget Amendment Necessary: Yes.

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

7a. Expenditure Impact:

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Positions</i>	<i>Fund</i>
2018	0		0
2019	\$1,194,150	7	NGF
2020	\$1,194,150	7	NGF
2021	\$1,194,150	7	NGF
2022	\$1,194,150	7	NGF
2023	\$1,194,150	7	NGF
2024	\$1,194,150	7	NGF

7b. Revenue Impact:

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2018	\$0	
2019	\$1,194,150	NGF
2020	\$1,194,150	NGF
2021	\$1,194,150	NGF
2022	\$1,194,150	NGF
2023	\$1,194,150	NGF
2024	\$1,194,150	NGF

8. Fiscal Implications: Funding for the Department of General Services (DGS) Division of Consolidated Laboratory Services (DCLS) newborn testing services as well as coordination and education services provided by the Virginia Department of Health (VDH) are recovered from a fee

charged to medical providers for each screening test. The current fee is \$78 per infant and would be adjusted to recover any additional costs incurred to expand the required screening. Based on the current estimated cost of \$1,194,150 to add screening for adding Pompe, MPS-1, Fabry and Gaucher, the fee would need to be raised by \$11.06, bringing the total new cost to \$89.06 per infant. This assumes 108,000 tests are performed annually, based on current testing volume.

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 DCLS or another laboratory contracted by VDH to provide testing services. VDH coordinates follow-up activities for newborns identified as at risk for tested disorders.

Department of General Services:

According to DGS, DCLS is expected to incur additional annual costs of \$1,106,150 to screen for the new disorders, primarily for laboratory staff and reagents. Different reagents are required in order to screen for the new disorders. Therefore, additional staff is needed to run tests using the different reagents required, including initial screening tests as well as confirmatory testing. Estimated costs include six additional scientists (\$406,000), testing reagents and other testing consumables (\$587,550), laboratory equipment maintenance costs for the additional equipment needed (\$109,600), and IT hardware (\$3,000).

DCLS also anticipates some additional costs to be incurred prior to implementation of the additional screening; however, it anticipates being able to absorb such costs. This is primarily associated with the purchase of additional equipment and time needed to hire and train staff and for new staff to complete the competencies required for accreditation, all of which is expected to take approximately six months.

Virginia Department of Health:

The VDH newborn screening follow-up program is responsible for reporting critical results to providers within 24 hours following notification of result and to coordinate referrals for diagnostic or repeat testing. Additional staffing of one registered nurse (total compensation \$88,000) will be needed for the projected increased volume of tests requiring follow-up. Virginia's newborn screening educational website will be updated with content on the new disorders and can be absorbed within existing resources.

- 9. Specific Agency or Political Subdivisions Affected:** Virginian Department of Health, Department of General Services' Division of Consolidated Laboratory Services, and birthing hospitals, midwives and other healthcare providers.

- 10. Technical Amendment Necessary:** No

- 11. Other Comments:** HB 1174, introduced by Delegate Pillion, is a companion bill.