

Department of Planning and Budget
2026 General Assembly Session
State Fiscal Impact Statement

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ORIGINAL

Bill Number: SB374S2

Patron: Boysko

Bill Title: Newborn screening requirements

Bill Summary: This legislation, as amended in the nature of a substitute, requires the Virginia Department of Health (VDH) to amend regulations governing newborn screening to include screening for Gaucher disease. The inclusion of Gaucher disease is exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) as well as any evaluation and rulemaking procedures outlined in § 32.1-65 of the Code of Virginia.

Budget Amendment Necessary: Yes

Items Impacted: 68

Explanation: The Department of General Services (DGS) Division of Consolidated Laboratory Services (DCLS) and would require additional nongeneral fund appropriation attributable to Item 68 (DGS). The total fiscal impact on the Virginia Department of Health cannot be determined.

Fiscal Summary: The inclusion of Gaucher disease on the newborn screening panel would have a fiscal impact on the Department of General Services' Division of Consolidated Laboratory Services (DCLS). DCLS indicates a fiscal impact of \$2,186,642 in the first year and \$1,331,442 in following years due to IT, personnel, and lab infrastructure costs. DCLS does not perform Gaucher disease testing on any of its current platforms and to implement the provisions of the legislation, several operational and technical factors must align.

These factors include lab infrastructure (equipment and validation protocols--\$1,524,000 in the first year and \$192,000 for maintenance support in outyears), an update of the Laboratory Information Management System (\$50,000 first year and \$5,000 in following years), HIPAA-compliant result reporting, e-reporting with hospitals, training specialized scientists to handle the increased test volume and technical complexity of the screenings (3 FTEs, \$495,742 annually), and procurement of reagents and instrumentation (\$115,000 startup and \$636,000 in following years). Additionally, the Division anticipates an additional \$1,900 to prepare and distribute the report stipulated in the bill.

Notably, DCLS indicates they cannot control the timeline of when the previously listed components are available and ready for operation. The Division indicates that screening is not possible until Q4 2028, after the legislation is enacted on July 1, 2026.

Additionally, the bill exempts the inclusion of Gaucher disease from the evaluation and rulemaking processing. Therefore, no immediate fiscal impact on VDH is expected as they are not required to perform any such evaluation usually done for disorders not on the federal Recommended Uniform Screening Panel. Based on data from other states that screen for Gaucher disease, the number of test results that would require action by VDH is not estimated to be significant. Should the number of tests that require follow-up be higher than anticipated, VDH may need additional resources which would be included in any fee adjustments by DCLS but are not included in this estimate.

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Nongeneral Fund Expenditure Impact:

| <u>Agency</u> | <u>FY2026</u> | <u>FY2027</u> | <u>FY2028</u> | <u>FY2029</u> | <u>FY2030</u> | <u>FY2031</u> |
|----------------|---------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| VDH (601) | - | Indeterminate | Indeterminate | Indeterminate | Indeterminate | Indeterminate |
| DGS-DCLS (194) | - | \$2,186,642 | \$1,331,442 | \$1,331,442 | \$1,331,442 | \$1,331,442 |
| TOTAL | - | \$2,186,642 | \$1,331,442 | \$1,331,442 | \$1,331,442 | \$1,331,442 |

Revenue Impact:

| <u>Agency</u> | <u>FY2026</u> | <u>FY2027</u> | <u>FY2028</u> | <u>FY2029</u> | <u>FY2030</u> | <u>FY2031</u> |
|----------------|---------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| VDH (601) | - | Indeterminate | Indeterminate | Indeterminate | Indeterminate | Indeterminate |
| DGS-DCLS (194) | - | \$2,186,642 | \$1,331,442 | \$1,331,442 | \$1,331,442 | \$1,331,442 |
| TOTAL | - | \$2,186,642 | \$1,331,442 | \$1,331,442 | \$1,331,442 | \$1,331,442 |

Position Impact:

| <u>Agency</u> | <u>FY2026</u> | <u>FY2027</u> | <u>FY2028</u> | <u>FY2029</u> | <u>FY2030</u> | <u>FY2031</u> |
|----------------|---------------|---------------|---------------|---------------|---------------|---------------|
| VDH (601) | - | Indeterminate | Indeterminate | Indeterminate | Indeterminate | Indeterminate |
| DGS-DCLS (194) | - | 3 | 3 | 3 | 3 | 3 |
| TOTAL | - | 3 | 3 | 3 | 3 | 3 |

Fiscal Analysis: The Newborn Screening (NBS) Program is entirely supported through fees charged to hospitals for test kits. Assuming a test volume of 95,000 tests, a fee increase of \$23/test the first year and \$14/test in following years will be required to recover costs to screen for Gaucher disease (\$161 and \$152 for the total kit, respectively). These costs are not inclusive of work performed by VDH which may increase the fee.

The cost estimates in the Fiscal Summary assume that equipment and reagents were obtained from a vendor. Personnel estimates are based on current salaries/benefits for similar positions. Fringes are assumed at 30%. The first FTE needed (\$156,468) is a Lead Scientist that coordinates and provides oversight into the development and implementation of Gaucher testing, provides technical guidance and support for method validation, strategic direction for new and emerging disorders, risk management, and leads multidisciplinary teams. The second position is a Newborn Screening Principal Scientist (\$131,274) that assesses and makes determinations on the feasibility and criteria to evaluate Gaucher tests, implements hands-on method development and verification, performs troubleshooting for technical methods, software, and instrumentation, manages technical projects, and oversees screening operations day to day. The third position is an IT support position (\$208,000) that analyzes, designs, implements, and tests Laboratory Information Management System workflows to ensure the Gaucher test results are received in the hospital system.

The responsibilities of the FTEs will also pertain to disorders beyond Gaucher. While they are essential to ensuring DCLS can meet the implementation timeline of the legislation, the positions also develop infrastructure needed for future disorder additions.

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The fiscal impact on the Department of Medical Assistance Services should Gaucher disorder be added to the newborn screening panel cannot be determined as the agency could experience an increase in follow-up screenings and additional treatment costs.

Other: None