

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

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ORIGINAL

Bill Number: HB433H1

Patron: LeVere Bolling

Bill Title: Newborn screening requirements

Bill Summary: Requires the Virginia Department of Health (VDH) to conduct evaluations for additional disorders not included on the federal Recommended Uniform Screening Panel to determine whether such additional disorders should be included under the Commonwealth's newborn screening program.

Budget Amendment Necessary: Yes

Items Impacted: 68 and 277

Explanation: The Department of General Services (DGS) Division of Consolidated Laboratory Services (DCLS) and the Virginia Department of Health will require additional nongeneral fund appropriation and positions to comply with the provisions of this legislation, attributable to Item 68 (DGS) and Item 277 (VDH).

Fiscal Summary: VDH's Virginias Newborn Screening Program (VNBSP) currently operates through fee revenue received for providing newborn screening services. Current fee revenue is collected by DGS-DCLS in a special fund and is used to support program costs, including personnel, at VDH. The provisions of this legislation would generate additional revenue that would need to be appropriated at VDH and DGS. It is expected that the estimated revenue is sufficient to offset expected costs. Both agencies report that additional nongeneral positions would also be necessary.

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) | - | \$123,701 | \$123,701 | \$123,701 | \$123,701 | \$123,701 |
| DGS-DCLS (194) | - | \$2,248,608 | \$2,248,608 | \$2,248,608 | \$2,248,608 | \$2,248,608 |
| TOTAL | - | \$2,372,307 | \$2,372,307 | \$2,372,307 | \$2,372,307 | \$2,372,307 |

Revenue Impact:

| <u>Agency</u> | <u>FY2026</u> | <u>FY2027</u> | <u>FY2028</u> | <u>FY2029</u> | <u>FY2030</u> | <u>FY2031</u> |
|----------------|---------------|------------------|--------------------|--------------------|--------------------|--------------------|
| DGS-DCLS (194) | - | \$282,637 | \$2,372,307 | \$2,372,307 | \$2,372,307 | \$2,372,307 |
| TOTAL | - | \$282,637 | \$2,372,307 | \$2,372,307 | \$2,372,307 | \$2,372,307 |

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) | - | 1 | 1 | 1 | 1 | 1 |
| DGS-DCLS (194) | - | 1 | 4 | 4 | 4 | 4 |
| TOTAL | - | 2 | 5 | 5 | 5 | 5 |

Fiscal Analysis: The provisions of this legislation, as amended, would require VDH to "establish a process for considering the addition of other disorders to the Commonwealth's screening program that are not included on the RUSP." To establish this process, VDH would design this process, in collaboration with stakeholders, and then implement a review process for non-RUSP disorders.

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VDH reports that an administrative specialist will be needed to support the VNBSP in the review of new and rare disorders meeting the criteria included in the bill and to manage the process and procedures relevant to their review, including workgroup support and leading the rule making process. The cost for this position, including salary and fringe benefits, is estimated to be \$123,700 beginning in FY 2027.

The provisions of the bill require the establishment of a process for considering the addition of other disorders to the Commonwealth's screening program that are not included on the RUSP. It is assumed that DGS-DCLS would contract with a clinical specialist as necessary to establish such process. DGS-DCLS maintains that this can be absorbed with modifications to the existing fee schedule.

Since DGS-DCLS performs the actual screenings for the VNBSP, staff from DGS-DCLS will work closely with VDH on process development as well. DGS-DCLS maintains that it will require funding for one lead scientist position to coordinate efforts with VDH and lead the process from the DGS-DCLS evaluation and testing perspective. The cost for this position, including salary and fringe benefits, is \$159,468.

The bill states that for any disorder evaluated pursuant to the process established by this bill, reevaluation should occur as necessary by conducting a review of medical literature, providing for public input, conducting evaluations annually, and commencing the rulemaking process for the consideration of a disorder. It is assumed that VDH would utilize the expertise of DGS-DCLS for additional evaluations.

Once the evaluations of disorders begin, per the requirements of the bill, DGS-DCLS reports that it will require an additional three positions. The cost for these positions, including salary and fringe benefits, is as follows:

- Lead Scientist (\$159,468): To work with the first Lead Scientist to direct and coordinate the continuous scientific evaluation of new and rare disorders.
- Program Technician (\$75,930): To manage documentation, tracking, and operational support for the technical review process and other related programmatic needs.
- Quality Assurance Principal Scientist (\$134,274): To assess and make determinations as to the feasibility and criteria required to properly validate new laboratory tests for rare disorders.

Given the wide range of disorders that could require evaluation, as well as peer review publications, DGS-DCLS estimates that 2,080 ongoing consulting hours are needed, which would cost \$1,040,000. There are potentially dozens of rare disorders that could require evaluation under this legislation. Therefore DGS-DCLS would utilize consulting services with multiple scientists with different areas of expertise to assist with this effort.

The current cost to screen one panel is \$138. Using an annual birth rate of 95,000 based on recent vital records data, the fee would increase by \$24.97 to cover the provisions of the bill.

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The total cost of the bill is expected to be \$2,372,307 (\$123,701 VDH and \$2,248,608 DGS-DCLS) in FY 2027 and thereafter. DGS-DCLS is expected to generate sufficient fee revenue to entirely support these costs. Both agencies would require the appropriation on this nongeneral fund revenue, along with the additional positions.

Other: None