

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

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**ORIGINAL**

**Bill Number:** HB433S1

**Patron:** LeVere Bolling

**Bill Title:** Newborn screening requirements

**Bill Summary:** The bill, as amended in the nature of a substitute, requires the Virginia Department of Health (VDH) to conduct evaluations for additional disorders not included on the federal Recommended Uniform Screening Panel (RUSP) to determine whether such additional disorders should be included under the Commonwealth's newborn screening program. As amended, the bill states that no disorder shall be added to the Commonwealth's screening program or any necessary evaluation be performed unless an appropriation has been provided by the General Assembly for this purpose.

**Budget Amendment Necessary:** Yes

**Items Impacted:** 68 and 277

**Explanation:** The total fiscal impact the provisions of the bill would have on the Commonwealth cannot be determined. The bill states that no disorder shall be added to the Commonwealth's screening program or any necessary evaluation be performed unless an appropriation has been provided by the General Assembly for this purpose.

**Fiscal Summary:** 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. VDH must consult with the Newborn Screening Advisory Committee to develop a process to determine whether such disorders should be included for evaluation. If a disorder is recommended for evaluation, VDH would need one-time general fund support in the first year to consult with clinical specialist to perform each such evaluation and only if such funding is provided by the General Assembly for this purpose.

It is unknown how many disorders would be recommended by VDH or the Newborn Screening Advisory Committee for evaluation. Should any disorder be recommended, general fund appropriation would be required in the first year to support the evaluation. VDH and DCLS may need nongeneral fund appropriation in subsequent years for any additional revenue received.

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. While DCLS has the ability to increase fees for each disorder added to the newborn screening panel, it is unknown if any additional disorders would ultimately be added to the newborn screening panel. Therefore, it is unknown if there is a need for a fee increase.

Additionally, the bill states that no disorder shall be added to the Commonwealth's screening program or any necessary evaluation be performed unless an appropriation has been provided by the General Assembly for this purpose.

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**General 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	-	-	-	-
<b>TOTAL</b>	-	Indeterminate	-	-	-	-

**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
DGS-DCLS (194)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
<b>TOTAL</b>	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate

**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
DGS-DCLS (194)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
<b>TOTAL</b>	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate

**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
DGS-DCLS (194)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
<b>TOTAL</b>	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate

**Fiscal Analysis:**

Disorder Recommendation

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. The bill would require VDH to consult with the Newborn Screening Advisory Committee to develop a process to determine whether such disorders should be recommended for evaluation. If a disorder is recommended for evaluation, VDH would need one-time general fund support in the first year to consult with clinical specialists to perform such evaluation. The amount of such support would depend on the number and complexity of disorders selected for evaluation. It is unknown if any disorders would be recommended for evaluation. The bill states that no disorder shall be added to the Commonwealth's screening program or any necessary evaluation be performed unless an appropriation has been provided by the General Assembly for this purpose.

Disorder Evaluation

VDH's Office of Family Health Services (OFHS), which oversees the VNBS, has not historically reviewed non-RUSP disorders for inclusion on the newborn screening panel. The federal entity that previously conducted rigorous disorder reviews, the Advisory Committee for Heritable Disorders in Newborns and Children, was terminated by the U.S. Department of Health and Human Services (HHS) in April 2025. This means that OFHS

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would be responsible for identifying and synthesizing clinical research on such disorders, screenings, diagnostics, and treatments along with convening expert workgroups, preparing reports, and other related activities.

VDH and DGS-DCLS do not have sufficient expertise to conduct the advanced scientific research and clinical evaluation necessary for non-RUSP disorders and would require contracting with specialty clinical consultants. Clinical specialists would provide subject matter expertise on disorder diagnosis, care management, treatment requirements in addition to evaluating documentation and compiled resources.

There are potentially dozens of rare disorders that could require evaluation under this legislation. Therefore, VDH and DGS-DCLS would utilize consulting services with multiple scientists with different areas of expertise to assist with this effort. Based on independent estimates, costs for one evaluation range from \$300,000 to \$900,000 or more, depending on the complexity of the disorder and any specialized diagnostics needed. Total costs would vary depending on the number of disorders evaluated in a given year.

VDH and DGS-DCLS partner to conduct disorder evaluations. However, VDH consultants' needs for clinical specialists are separate and distinct from the needs of DGS-DCLS. DGS-DCLS would focus on gathering information on technical specifications of testing and screening of potential disorders, including reviewing new and emerging testing methodologies and validating laboratory processes. VDH focuses on disorder diagnosis, care management, treatment, and follow-up. Therefore, both agencies would require consultant services that specialize and focus on different aspects of evaluation and disorder review. Should any disorder be added to the newborn screening panel, ongoing costs associated with screening and program administration would shift to nongeneral funds and would be supported by fee revenue.

VDH reports that an administrative specialist would 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 rulemaking process. The cost for such a position, including salary and fringe benefits, is estimated to be approximately \$125,000.

Since DGS-DCLS performs the actual screenings for the VNBSP, staff from DGS-DCLS would work closely with VDH on process development as well. DGS-DCLS maintains that it would 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 such a position, including salary and fringe benefits, would be approximately \$160,000.

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 and DGS-DCLS would utilize the expertise of clinical consultants for this effort.

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The current cost to screen one panel is \$138. Should any disorder be added to the newborn screening panel, the fee would be adjusted as necessary to cover any increase in costs. Accordingly, while evaluation and start-up costs may require general fund support, ongoing screening costs would be supported through fee revenue.

Lastly, the bill states that no disorder shall be added to the Commonwealth's screening program or any necessary evaluation be performed unless an appropriation has been provided by the General Assembly for this purpose.

**Other:** None