Department of Planning and Budget
2025 General Assembly Session
State Fiscal Impact Statement

PUBLISHED: 1/24/2025 3:08 PM **Revised**

Bill Number: HB1782 **Patron:** Sullivan
Bill Title: Newborn screening requirements; federal Recommended Uniform Screening Panel; evaluation; rulemaking; report.

Bill Summary: Directs the Department of Health (the Department) to determine whether testing for disorders included on the federal Recommended Uniform Screening Panel (RUSP) recommended by the Secretary of the U.S. Department of Health and Human Services should be included in the Commonwealth's newborn screening requirements. The bill directs the Department to evaluate disorders included on the RUSP within 12 months of their addition to the RUSP and commence rulemaking procedures for adding such disorders to the Commonwealth's screening program if their inclusion is appropriate. The bill also requires the Department to determine annually whether disorders not included in the Commonwealth's newborn screening program should be reevaluated for inclusion. The bill requires the Department to submit a status report to the General Assembly annually containing information on the disorders included, evaluated, not recommended for inclusion, and not recommended for reevaluation. The bill contains an enactment clause requiring the Department to conduct such evaluation and, if applicable, commence rulemaking procedures for the addition of disorders within 12 months of the effective date of the bill for any disorders that are listed on the RUSP as of January 1, 2025.

Budget Amendment Necessary: Yes **Items Impacted:** VDH – 277, DGS/DCLS - 68

Fiscal Summary: The provisions of the bill expand the requirements of the Virginia Department of Health's (VDH) Virginia Newborn Bloodspot Screening Program (VNBSP) related to adding new disorders to the Commonwealth's newborn screening bloodspot panel following the addition of a disorder to the federal Recommended Uniform Screening Panel (RUSP). The RUSP is put forth by the U.S. Secretary of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

Specifically, the bill would require VDH to review any new disorders added to the federal RUSP within 12 months of addition to the RUSP and consider adding them to the Virginia panel. It would require the Department to implement screening for any new disorders that are approved to be added to the Virginia panel within 36 months after the disorder is added the federal RUSP. If disorders are reviewed and not recommended for implementation in Virginia, the bill would require VDH to continue to review the disorder on an annual basis.

Additionally, the bill requires the VNBSP to submit an annual report to the General Assembly to include; 1) a list of current disorders screened for on Virginia's panel; 2) disorders under consideration for inclusion to the panel, 3) disorders reviewed but not recommended for inclusion and justification against inclusion; 4) disorders previously reviewed which did not receive the annual reevaluation and justification against

reevaluation; and 5) an account of any delays in compliance with the updated timeframes specified by the bill for evaluation, inclusion, or reevaluation of disorders and the reason for any delays.

The bill also contains an enactment clause, which will require VDH to begin all activities detailed above within 12-months of the effective date of the bill for any disorders listed on the RUSP as of January 1, 2025. As of January 2023, there were 66 core and secondary disorders on the RUSP, newer conditions are still in the process of adoption. The bill grants permission to VDH to charge a reasonable fee for tests performed pursuant to this act.

General Fund Expenditure Impact:

Agency	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030
V**DH**		$121,017	$121,017	$121,017	$121,017	$121,017
TOTAL		**$121,017**	**$121,017**	**$121,017**	**$121,017**	**$121,017**

Nongeneral Fund Expenditure Impact:

Agency	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030
DGS		$353,883	$353,883	$353,883	$353,883	$353,883
TOTAL		**$353,883**	**$353,883**	**$353,883**	**$353,883**	**$353,883**

Fiscal Analysis for the Virginia Department of Health: VDH does not currently have the staff capacity to meet the timelines and frequency of reviews outlined in the bill, as well as the additional requirements for the VNBSP team (e.g., reporting). VDH would need general fund support for one position to meet the requirements of the legislation.

The VDH Newborn Blood Spot Screening Program, including staff, is currently funded through Division of Consolidated Laboratory Services (DCLS) through special revenue funding. This special revenue funding comes from the collection of fees from the current cost of the newborn screening test. Although DCLS may increase its fees for adding new disorders to the newborn screening panel, it is unknown if they will choose to increase fees as a result of this bill. VDH does not have the infrastructure to charge and collect a fee for testing. Given that uncertainty, VDH would still be required do the additional work and meet specified timelines as required by the without an increase in revenue.

VDH would use the additional support to hire a program specialist that would be dedicated to the implementation of the requirements of the bill. Specifically, they will ensure timelines are met by VDH and DCLS for review, support new disorder considerations, manage the regulatory process for any needed changes, and compile multiple reports including reports on the work group reviews and the annual report to the General Assembly. This position is estimated to cost $121,017, which includes salary, fringe benefits, and VITA charges. In the event DCLS increases the fee as a result of this bill, NGF revenue should be used to sustain this position.

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Fiscal Analysis for the Department of General Services: The Department of General Services' Division of Consolidated Laboratory Services (DCLS) indicates a fiscal impact of $353,883 to be realized in the DCLS NGF enterprise fund 05010. DCLS requests a lead scientist and project manager with full salary, benefits, and equipment costs. HB1782 amends the Code of Virginia § 32.1-65 to require the Virginia Department of Health (Department) to evaluate disorders included on the RUSP within 12 months of their addition and commence rulemaking procedures for adding such disorders to the Commonwealth's screening program if their inclusion is appropriate and implement testing within 6 months following approval.

Given the expedited timeline requirements for review and implementation of new disorders and testing, DCLS will require a dedicated Lead Scientist FTE with associated fringe and equipment costs. This FTE is responsible for scientific evaluation and guidance for the development and implementation of genetic testing, as well as result interpretation for newborn disorders. The individual will ensure timeline compliance, communications with programmatic team members, and preparation of validation packages for internal DCLS review and external FDA review:

Position Title: Scientist III - Lead Scientist = $145,951/year (salary and fringe), VITA Agency Charges for Personnel: $2,940/year, Office Equipment (monitor, docking station, etc): $675, Office furniture (desk, chair, bookcase): $5,062, Office Space Rent ($28.14/sqft): $3,377/year

DCLS' IT infrastructure is currently insufficient to accommodate additional types of testing in the newborn screening panel. If DCLS is to follow the provisions of the bill with current IT resources, delays may occur in incorporating new tests into the panel. Newborn screening samples must be processed through the Laboratory Information Management System (LIMS), the DCLS application to transmit sample information from hospitals to be tested at DCLS and subsequently the secure transmission of test results back to hospitals. The timeline to develop workflow configurations, conduct validation testing, and implement changes in LIMS is impacted by available resources. To minimize delays as a result of available resources, one non-general fund FTE in the enterprise fund 05010 will be required to hire a newborn screening project manager to meet the implementation timeline. Additionally, based on the stipulated LIMS configuration changes to support test implementation, there is an indeterminate fiscal impact in future years for additional IT support:

Position Title: NBS ISS Project Manager = $192,938 (salary and fringe), VITA Agency Charges for Personnel: $2,940/year

The current NBS Program operates from revenue received from the purchase of collection devices (Enterprise Fund). Therefore, the addition of these two (2) FTEs and associated costs (equipment, furniture, rent) will require DCLS to increase the NBS fee for collection devices. The total cost of the two NGF FTEs (salary, fringes, equipment) is $353,883. In order to sufficiently recover costs for the program, the additional personnel would necessitate an increase of the fee charged on newborn screening collection devices from the current $138.00 to $141.73.

The bill grants permission to VDH to charge a reasonable fee for tests performed pursuant to this act. However, the current regulations (12VAC5-71-100) state the testing laboratory is authorized to set the fee

charged to birthing hospitals and physicians for purchase of newborn dried-blood-spot screening specimen collection kits in consultation with the department and in accordance with applicable state statutes and regulations.

Other: This fiscal impact statement has been revised upon receiving additional information from the Department of General Services' Division of Consolidated Laboratories.