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HOUSE BILL NO. 433

Offered January 14, 2026

Prefiled January 12, 2026

A BILL to amend and reenact § 32.1-65 of the Code of Virginia, relating to newborn screening; evaluation of disorders for inclusion.

Patron—LeVere Bolling

Committee Referral Pending

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-65 of the Code of Virginia is amended and reenacted as follows:

§ 32.1-65. Certain newborn screening required.

A. For the purposes of this section, "RUSP" means the federal Recommended Uniform Screening Panel recommended by the Secretary of the U.S. Department of Health and Human Services.

B. In order to prevent intellectual disability and permanent disability or death, every infant who is born in the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not necessarily identical to, the RUSP recommended by the U.S. Secretary of Health and Human Services ~~and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children~~.

C. The Department shall ensure that testing for any disorder that is included on the RUSP as of January 1, 2025, is included in the testing required under this section if determined appropriate by the Department. For any disorder included on the RUSP, the Department shall:

1. Conduct an evaluation to determine whether the disorder should be included on the Commonwealth's screening program, including an assessment of the estimated costs of including the disorder and a fiscal impact on the fee for the tests performed; and

2. If the Department determines the disorder should be included in the testing required under this section, commence the rulemaking process to add the disorder to the Commonwealth's screening program.

The Department shall conduct such evaluation and commence such rulemaking process, if applicable, within 12 months of the addition of any disorder added to the RUSP after January 1, 2025. If a condition is added to the Commonwealth's screening panel by rule, and there is an available test that meets all federal and state laboratory requirements for newborn screening programs, the Department shall implement screening for the condition in the Commonwealth's screening program within six months of completion of the rulemaking process. If there is not an available test that meets state and federal laboratory requirements for newborn screening programs, the program shall secure an appropriate test as soon as available.

D. For any disorder *(i)* included on the RUSP *or (ii) evaluated pursuant to subsection E* that the Department determines in an initial evaluation should not be included under the Commonwealth's screening program, the Department shall determine whether reevaluation is necessary by (i) reviewing the medical literature published on the disorder since the initial evaluation and (ii) allowing for public input. The Department shall conduct such determination annually. If the Department determines reevaluation is necessary during such annual determination, the Department shall conduct an evaluation and commence the rulemaking process, if applicable, within 12 months pursuant to subsection C. The Department shall not include in the testing required under this section any disorder not included on the RUSP unless it has first conducted an evaluation and commenced the rulemaking process to add the disorder in the same manner as is required for any disorder included on the RUSP in accordance with subsection C.

E. *In addition to disorders included on the RUSP, the Department shall conduct an evaluation for any disorder with (i) an available assay for newborn screening and (ii) a treatment in phase III clinical trials or approved for a rare condition by the federal Food and Drug Administration to determine whether such disorder should be included in the testing required under this section. The Department shall conduct such evaluation and, if applicable, commence the rulemaking process to add such disorder to the testing required under this section in the same manner as is required for any disorder included on the RUSP in accordance with subsection C.*

1. The Department shall conduct evaluation and rulemaking pursuant to this subsection in accordance with a schedule of evaluation that is determined in consultation with the Newborn Screening Subcommittee of the Genetics Advisory Committee and the Rare Disease Council. In developing such schedule of evaluation, the Department shall prioritize disorders that:

a. (i) Have demonstrated benefit of early intervention, (ii) are in alignment with existing technology, and (iii) have a treatment in phase III clinical trials or approved for a rare condition by the federal Food and Drug Administration or have therapeutic guidelines for treatment; or

b. Are already recommended for inclusion on the RUSP.

2. The Department shall include disorders evaluated pursuant to this subsection in its report submitted pursuant to subsection F.

F. The Department shall submit a status report to the General Assembly on the screening program annually. Such status report shall include:

1. The current disorders included under the Commonwealth's screening program;

2. Any new disorders currently under consideration or recommended for inclusion under the Commonwealth's screening program;

3. Any new disorders considered but not recommended for inclusion in the Commonwealth's screening program in the prior 12-month period and the reason for not recommending such disorders;

4. Any disorders for which the Department determined a reevaluation was unnecessary in the prior 12-month period and the reason that such reevaluation is not necessary at the time of such determination; and

5. Any delay in complying with the timeframes specified by this section for evaluation, inclusion, or reevaluation of a disorder and the reason for such delay.

~~F.~~ *G.* Any infant whose parent or guardian objects thereto on the grounds that such tests conflict with his religious practices or tenets shall not be required to receive such screening tests.

~~G.~~ *H.* The physician, licensed midwife, or certified nurse midwife in charge of the infant's care after delivery shall cause such tests to be performed. The screening tests shall be performed by the Division of Consolidated Laboratory Services or any other laboratory the Department of Health has contracted with to provide such service. Screening tests for time-critical disorders identified by the U.S. Department of Health and Human Services ~~and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children~~ shall be performed seven days a week.

~~H.~~ *I.* The program for screening infants for sickle cell diseases shall be conducted in addition to the programs provided for in Article 8 (§ 32.1-68 et seq.).

2. That the Department of Health shall conduct an evaluation to determine whether the following disorders should be included in the Commonwealth's newborn screening panel: (i) Sanfilippo syndrome type A (MPS IIIA); (ii) Morquio syndrome type A (MPS IVA); (iii) Maroteaux-Lamy syndrome (MPS VI); (iv) Sly syndrome (MPS VII); (v) Batten disease type 2 (CLN2); (vi) Fabry disease; (vii) Gaucher disease; (viii) acid sphingomyelinase deficiency (ASMD); and (ix) any other conditions that have been approved by the RUSP, as defined in § 32.1-65 of the Code of Virginia, as amended by this act, but are not yet included on the Virginia newborn screening panel. The Department shall conduct such evaluation pursuant to and include such evaluation in the reporting required by § 32.1-65 of the Code of Virginia, as amended by this act.