

26104863D

SENATE BILL NO. 374

Offered January 14, 2026

Prefiled January 13, 2026

A BILL to amend and reenact § 32.1-65 of the Code of Virginia, relating to newborn screening requirements; Gaucher disease.

 Patron—Boysko

 Referred to Committee on Education and Health

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 included on the RUSP 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 approved for a rare condition by the U.S. 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.*

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

INTRODUCED

SB374

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

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

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

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

71 **2. That the Department of Health (the Department) shall conduct an evaluation to determine whether**
72 **Gaucher disease should be included in the Commonwealth's newborn screening panel. The**
73 **Department shall conduct such evaluation pursuant to and include such evaluation in the reporting**
74 **required by § 32.1-65 of the Code of Virginia, as amended by this act.**