

1 VIRGINIA ACTS OF ASSEMBLY — CHAPTER

2 *An Act to amend and reenact § 32.1-65 of the Code of Virginia, relating to newborn screening; evaluation of*
 3 *disorders for inclusion.*

4 [H 433]

5 Approved

6 **Be it enacted by the General Assembly of Virginia:**7 **1. That § 32.1-65 of the Code of Virginia is amended and reenacted as follows:**8 **§ 32.1-65. Certain newborn screening required.**9 A. For the purposes of this section, "RUSP" means the federal Recommended Uniform Screening Panel
 10 recommended by the Secretary of the U.S. Department of Health and Human Services.11 B. In order to prevent intellectual disability and permanent disability or death, every infant who is born in
 12 the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not
 13 necessarily identical to, the RUSP recommended by the U.S. Secretary of Health and Human Services ~~and the~~
 14 ~~Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.~~15 C. The Department shall ensure that testing for any disorder that is included on the RUSP as of January 1,
 16 2025, is included in the testing required under this section if determined appropriate by the Department. For
 17 any disorder included on the RUSP, the Department shall:18 1. Conduct an evaluation to determine whether the disorder should be included on the Commonwealth's
 19 screening program, including an assessment of the estimated costs of including the disorder and a fiscal
 20 impact on the fee for the tests performed; and21 2. If the Department determines the disorder should be included in the testing required under this section,
 22 commence the rulemaking process to add the disorder to the Commonwealth's screening program.23 The Department shall conduct such evaluation and commence such rulemaking process, if applicable,
 24 within 12 months of the addition of any disorder added to the RUSP after January 1, 2025. If a condition is
 25 added to the Commonwealth's screening panel by rule, and there is an available test that meets all federal and
 26 state laboratory requirements for newborn screening programs, the Department shall implement screening for
 27 the condition in the Commonwealth's screening program within six months of completion of the rulemaking
 28 process. If there is not an available test that meets state and federal laboratory requirements for newborn
 29 screening programs, the program shall secure an appropriate test as soon as available.30 D. For any disorder (i) included on the RUSP or (ii) *evaluated pursuant to the process established by*
 31 *subsection E* that the Department determines in an initial evaluation should not be included under the
 32 Commonwealth's screening program, the Department shall determine whether reevaluation is necessary by (i)
 33 (a) reviewing the medical literature published on the disorder since the initial evaluation and (ii) (b) allowing
 34 for public input. The Department shall conduct such determination annually. If the Department determines
 35 reevaluation is necessary during such annual determination, the Department shall conduct an evaluation and
 36 commence the rulemaking process, if applicable, within 12 months pursuant to subsection C. The Department
 37 shall not include in the testing required under this section any disorder not included on the RUSP unless it has
 38 first conducted an evaluation and commenced the rulemaking process to add the disorder in the same manner
 39 as is required for any disorder included on the RUSP in accordance with subsection C.40 E. *In addition to disorders included on the RUSP, the Department shall establish a process for*
 41 *considering the addition of other disorders to the Commonwealth's screening program that are not included*
 42 *on the RUSP. The process shall include (i) criteria for which disorders shall be considered, including the*
 43 *availability of a newborn screening assay and a treatment approved by the U.S. Food and Drug*
 44 *Administration, (ii) a timeline for consideration of these disorders, and (iii) a timeline for initiating*
 45 *rulemaking following the consideration of a disorder. The Department shall consult with the Newborn*
 46 *Screening Advisory Committee and other relevant stakeholders as deemed appropriate by the Department in*
 47 *developing this process.*48 F. The Department shall submit a status report to the General Assembly on the screening program
 49 annually. Such status report shall include:

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

51 2. Any new disorders currently under consideration or recommended for inclusion under the
 52 Commonwealth's screening program;53 3. Any new disorders considered but not recommended for inclusion in the Commonwealth's screening
 54 program in the prior 12-month period and the reason for not recommending such disorders;55 4. Any disorders for which the Department determined a reevaluation was unnecessary in the prior 12-
 56 month period and the reason that such reevaluation is not necessary at the time of such determination; and

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

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

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

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

69 **2. That prior to considering any disorder for inclusion on the Commonwealth's screening panel not on**
70 **the federal Recommended Uniform Screening Panel (RUSP), the Department of Health shall complete**
71 **its evaluation and recommendation to the Commissioner of Health of any disorder added to the RUSP**
72 **prior to January 1, 2026, subject to funding.**