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HOUSE BILL NO. 1782

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Appropriations

on January 27, 2025)

(Patron Prior to Substitute—Delegate Sullivan)

A BILL to amend and reenact §§ 32.1-65 and 32.1-67 of the Code of Virginia, relating to newborn screening requirements; federal Recommended Uniform Screening Panel; evaluation; rulemaking; report.

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-65 and 32.1-67 of the Code of Virginia are 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 ~~uniform condition panel~~ 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. 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. 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. 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

60 and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and
61 Children shall be performed seven days a week.

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

64 **§ 32.1-67. Duty of Board for follow-up and referral protocols; regulations.**

65 Infants identified with any condition for which newborn screening is conducted pursuant to § 32.1-65 or
66 32.1-65.1 shall be eligible for the services of the Children with Special Health Care Needs Program
67 administered by the Department of Health. The Board of Health shall promulgate such regulations as may be
68 necessary to implement Newborn Screening Services and the Children with Special Health Care Needs
69 Program. The Board's regulations shall include, ~~but not be limited to,~~ a list of newborn screening tests
70 conducted pursuant to §§ 32.1-65 and 32.1-65.1 *and authorization to charge fees for such tests*, notification
71 processes conducted pursuant to § 32.1-66, follow-up procedures, appropriate referral processes, and services
72 available for infants and children who have a heritable disorder or genetic disease identified through
73 Newborn Screening Services.

74 **2. That the Department of Health (the Department) shall fulfill the requirements of subsection C of §**
75 **32.1-65 of the Code of Virginia, as amended by this act, within 12 months of the effective date of this**
76 **act for any disorders that are listed on the federal Recommended Uniform Screening Panel (RUSP) as**
77 **of January 1, 2025. If such a condition is added to the Commonwealth's screening panel by rule, the**
78 **program shall implement screening for the condition within six months of completion of the**
79 **rulemaking process. This enactment shall not apply to any disorder included on the RUSP that will be**
80 **included under the Commonwealth's screening program pending adoption of a regulation for which**
81 **the Department has commenced rulemaking procedures.**