

**As Introduced**

**131st General Assembly**

**Regular Session**

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**S. B. No. 14**

**Senators Faber, Lehner**

**Cosponsors: Senators Widener, Uecker, Gardner, Patton, Eklund, Jones**

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**A BILL**

To amend section 3701.501 of the Revised Code to 1  
require that Krabbe disease be included in the 2  
Newborn Screening Program. 3

**BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:**

**Section 1.** That section 3701.501 of the Revised Code be 4  
amended to read as follows: 5

**Sec. 3701.501.** (A) (1) Except as provided in division (A) 6  
(2) of this section, all newborn children shall be screened for 7  
the presence of the genetic, endocrine, and metabolic disorders 8  
specified in rules, adopted pursuant to this section. 9

(2) Division (A) (1) of this section does not apply if the 10  
parents of the child object thereto on the grounds that the 11  
screening conflicts with their religious tenets and practices. 12

(B) There is hereby created the newborn screening advisory 13  
council to advise the director of health regarding the screening 14  
of newborn children for genetic, endocrine, and metabolic 15  
disorders. The council shall engage in an ongoing review of the 16  
newborn screening requirements established under this section 17  
and shall provide recommendations and reports to the director as 18

the director requests and as the council considers necessary. 19  
The director may assign other duties to the council, as the 20  
director considers appropriate. 21

The council shall consist of fourteen members appointed by 22  
the director. In making appointments, the director shall select 23  
individuals and representatives of entities with interest and 24  
expertise in newborn screening, including such individuals and 25  
entities as health care professionals, hospitals, children's 26  
hospitals, regional genetic centers, regional sickle cell 27  
centers, newborn screening coordinators, and members of the 28  
public. 29

The department of health shall provide meeting space, 30  
staff services, and other technical assistance required by the 31  
council in carrying out its duties. Members of the council shall 32  
serve without compensation, but shall be reimbursed for their 33  
actual and necessary expenses incurred in attending meetings of 34  
the council or performing assignments for the council. 35

The council is not subject to sections 101.82 to 101.87 of 36  
the Revised Code. 37

(C) (1) The director of health shall adopt rules in 38  
accordance with Chapter 119. of the Revised Code specifying the 39  
disorders for which each newborn child must be screened. The 40  
rules shall specify Krabbe disease as a disorder for which a 41  
newborn child must be screened. 42

(2) The newborn screening advisory council shall evaluate 43  
genetic, metabolic, and endocrine disorders to assist the 44  
director in determining which disorders should be included in 45  
the screenings required under this section. In determining 46  
whether a disorder should be included, the council shall 47

consider all of the following:	48
(a) The disorder's incidence, mortality, and morbidity;	49
(b) Whether the disorder causes disability if diagnosis, treatment, and early intervention are delayed;	50 51
(c) The potential for successful treatment of the disorder;	52 53
(d) The expected benefits to children and society in relation to the risks and costs associated with screening for the disorder;	54 55 56
(e) Whether a screening for the disorder can be conducted without taking an additional blood sample or specimen.	57 58
(3) Based on the considerations specified in division (C) (2) of this section, the council shall make recommendations to the director of health for the adoption of rules under division (C) (1) of this section. The director shall promptly and thoroughly review each recommendation the council submits.	59 60 61 62 63
(D) The director shall adopt rules in accordance with Chapter 119. of the Revised Code establishing standards and procedures for the screenings required by this section. The rules shall include standards and procedures for all of the following:	64 65 66 67 68
(1) Causing rescreenings to be performed when initial screenings have abnormal results;	69 70
(2) Designating the person or persons who will be responsible for causing screenings and rescreenings to be performed;	71 72 73
(3) Giving to the parents of a child notice of the	74

required initial screening and the possibility that rescreenings may be necessary;	75 76
(4) Communicating to the parents of a child the results of the child's screening and any rescreenings that are performed;	77 78
(5) Giving notice of the results of an initial screening and any rescreenings to the person who caused the child to be screened or rescreened, or to another person or government entity when the person who caused the child to be screened or rescreened cannot be contacted;	79 80 81 82 83
(6) Referring children who receive abnormal screening or rescreening results to providers of follow-up services, including the services made available through funds disbursed under division (F) of this section.	84 85 86 87
(E) (1) Except as provided in divisions (E) (2) and (3) of this section, all newborn screenings required by this section shall be performed by the public health laboratory authorized under section 3701.22 of the Revised Code.	88 89 90 91
(2) If the director determines that the public health laboratory is unable to perform screenings for all of the disorders specified in the rules adopted under division (C) of this section, the director shall select another laboratory to perform the screenings. The director shall select the laboratory by issuing a request for proposals. The director may accept proposals submitted by laboratories located outside this state. At the conclusion of the selection process, the director shall enter into a written contract with the selected laboratory. If the director determines that the laboratory is not complying with the terms of the contract, the director shall immediately terminate the contract and another laboratory shall be selected	92 93 94 95 96 97 98 99 100 101 102 103

and contracted with in the same manner. 104

(3) Any rescreening caused to be performed pursuant to 105  
this section may be performed by the public health laboratory or 106  
one or more other laboratories designated by the director. Any 107  
laboratory the director considers qualified to perform 108  
rescreenings may be designated, including a laboratory located 109  
outside this state. If more than one laboratory is designated, 110  
the person responsible for causing a rescreening to be performed 111  
is also responsible for selecting the laboratory to be used. 112

(F) (1) The director shall adopt rules in accordance with 113  
Chapter 119. of the Revised Code establishing a fee that shall 114  
be charged and collected in addition to or in conjunction with 115  
any laboratory fee that is charged and collected for performing 116  
the screenings required by this section. The fee, which shall be 117  
not less than fourteen dollars, shall be disbursed as follows: 118

(a) Not less than ten dollars and twenty-five cents shall 119  
be deposited in the state treasury to the credit of the genetics 120  
services fund, which is hereby created. Not less than seven 121  
dollars and twenty-five cents of each fee credited to the 122  
genetics services fund shall be used to defray the costs of the 123  
programs authorized by section 3701.502 of the Revised Code. Not 124  
less than three dollars from each fee credited to the genetics 125  
services fund shall be used to defray costs of phenylketonuria 126  
programs. 127

(b) Not less than three dollars and seventy-five cents 128  
shall be deposited into the state treasury to the credit of the 129  
sickle cell fund, which is hereby created. Money credited to the 130  
sickle cell fund shall be used to defray costs of programs 131  
authorized by section 3701.131 of the Revised Code. 132

(2) In adopting rules under division (F) (1) of this section, the director shall not establish a fee that differs according to whether a screening is performed by the public health laboratory or by another laboratory selected by the director pursuant to division (E) (2) of this section.

**Section 2.** That existing section 3701.501 of the Revised Code is hereby repealed.

**Section 3.** This act shall be known as the "Madison Layton Act."