

**As Introduced**

**132nd General Assembly**

**Regular Session**

**2017-2018**

**H. B. No. 397**

**Representatives Boggs, Butler**

**Cosponsors: Representatives Antonio, Craig, Faber, Galonski, Kent, Koehler,  
Lepore-Hagan, Miller, Riedel**

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**A BILL**

To amend section 3701.501 of the Revised Code to 1  
include spinal muscular atrophy as an additional 2  
disorder to be screened for under the Newborn 3  
Screening Program. 4

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

**Section 1.** That section 3701.501 of the Revised Code be 5  
amended to read as follows: 6

**Sec. 3701.501.** (A) (1) Except as provided in division (A) 7  
(2) of this section, all newborn children shall be screened for 8  
the presence of the genetic, endocrine, and metabolic disorders 9  
specified in rules, adopted pursuant to this section. 10

(2) Division (A) (1) of this section does not apply in 11  
either of the following circumstances: 12

(a) If the parents of the child object to the screening on 13  
the grounds that it conflicts with their religious tenets and 14  
practices; 15

(b) With respect to the screening for Krabbe disease 16

described in division (C) (1) (b) of this section, if the parents 17  
of the child communicate their decision to forgo the screening. 18

(B) There is hereby created the newborn screening advisory 19  
council to advise the director of health regarding the screening 20  
of newborn children for genetic, endocrine, and metabolic 21  
disorders. The council shall engage in an ongoing review of the 22  
newborn screening requirements established under this section 23  
and shall provide recommendations and reports to the director as 24  
the director requests and as the council considers necessary. 25  
The director may assign other duties to the council, as the 26  
director considers appropriate. 27

The council shall consist of fourteen members appointed by 28  
the director. In making appointments, the director shall select 29  
individuals and representatives of entities with interest and 30  
expertise in newborn screening, including such individuals and 31  
entities as health care professionals, hospitals, children's 32  
hospitals, regional genetic centers, regional sickle cell 33  
centers, newborn screening coordinators, and members of the 34  
public. 35

The department of health shall provide meeting space, 36  
staff services, and other technical assistance required by the 37  
council in carrying out its duties. Members of the council shall 38  
serve without compensation, but shall be reimbursed for their 39  
actual and necessary expenses incurred in attending meetings of 40  
the council or performing assignments for the council. 41

The council is not subject to sections 101.82 to 101.87 of 42  
the Revised Code. 43

(C) (1) (a) Subject to ~~division~~divisions (C) (1) (b) and (c) 44  
of this section, the director of health shall adopt rules in 45

accordance with Chapter 119. of the Revised Code specifying the 46  
disorders for which each newborn child must be screened. 47

(b) In adopting the rules, the director shall specify 48  
Krabbe disease as a disorder for which a newborn child who is 49  
born on or after July 1, 2016, must be screened. The rules shall 50  
limit the screening requirement for Krabbe disease to the 51  
process known as "first tier testing," which is a screening for 52  
Krabbe disease that is accomplished by measuring 53  
galactocerebrosidase activity using mass spectrometry. 54

(c) In adopting the rules, the director shall specify 55  
spinal muscular atrophy as a disorder for which a newborn child 56  
who is born on and after the effective date of this amendment 57  
must be screened. 58

(2) The newborn screening advisory council shall evaluate 59  
genetic, metabolic, and endocrine disorders to assist the 60  
director in determining which disorders should be included in 61  
the screenings required under this section. In determining 62  
whether a disorder should be included, the council shall 63  
consider all of the following: 64

(a) The disorder's incidence, mortality, and morbidity; 65

(b) Whether the disorder causes disability if diagnosis, 66  
treatment, and early intervention are delayed; 67

(c) The potential for successful treatment of the 68  
disorder; 69

(d) The expected benefits to children and society in 70  
relation to the risks and costs associated with screening for 71  
the disorder; 72

(e) Whether a screening for the disorder can be conducted 73

without taking an additional blood sample or specimen. 74

(3) Based on the considerations specified in division (C) 75  
(2) of this section, the council shall make recommendations to 76  
the director of health for the adoption of rules under division 77  
(C) (1) of this section. The director shall promptly and 78  
thoroughly review each recommendation the council submits. 79

(D) The director shall adopt rules in accordance with 80  
Chapter 119. of the Revised Code establishing standards and 81  
procedures for the screenings required by this section. The 82  
rules shall include standards and procedures for all of the 83  
following: 84

(1) Causing rescreenings to be performed when initial 85  
screenings have abnormal results; 86

(2) Designating the person or persons who will be 87  
responsible for causing screenings and rescreenings to be 88  
performed; 89

(3) Giving to the parents of a child notice of the 90  
required initial screening and the possibility that rescreenings 91  
may be necessary; 92

(4) Communicating to the parents of a child the results of 93  
the child's screening and any rescreenings that are performed; 94

(5) Giving notice of the results of an initial screening 95  
and any rescreenings to the person who caused the child to be 96  
screened or rescreened, or to another person or government 97  
entity when the person who caused the child to be screened or 98  
rescreened cannot be contacted; 99

(6) Referring children who receive abnormal screening or 100  
rescreening results to providers of follow-up services, 101

including the services made available through funds disbursed 102  
under division (F) of this section. 103

(E) (1) Except as provided in divisions (E) (2) and (3) of 104  
this section, all newborn screenings required by this section 105  
shall be performed by the public health laboratory authorized 106  
under section 3701.22 of the Revised Code. 107

(2) If the director determines that the public health 108  
laboratory is unable to perform screenings for all of the 109  
disorders specified in the rules adopted under division (C) of 110  
this section, the director shall select another laboratory to 111  
perform the screenings. The director shall select the laboratory 112  
by issuing a request for proposals. The director may accept 113  
proposals submitted by laboratories located outside this state. 114  
At the conclusion of the selection process, the director shall 115  
enter into a written contract with the selected laboratory. If 116  
the director determines that the laboratory is not complying 117  
with the terms of the contract, the director shall immediately 118  
terminate the contract and another laboratory shall be selected 119  
and contracted with in the same manner. 120

(3) Any rescreening caused to be performed pursuant to 121  
this section may be performed by the public health laboratory or 122  
one or more other laboratories designated by the director. Any 123  
laboratory the director considers qualified to perform 124  
rescreenings may be designated, including a laboratory located 125  
outside this state. If more than one laboratory is designated, 126  
the person responsible for causing a rescreening to be performed 127  
is also responsible for selecting the laboratory to be used. 128

(F) (1) The director shall adopt rules in accordance with 129  
Chapter 119. of the Revised Code establishing a fee that shall 130  
be charged and collected in addition to or in conjunction with 131

any laboratory fee that is charged and collected for performing 132  
the screenings required by this section. The fee, which shall be 133  
not less than fourteen dollars, shall be disbursed as follows: 134

(a) Not less than ten dollars and twenty-five cents shall 135  
be deposited in the state treasury to the credit of the genetics 136  
services fund, which is hereby created. Not less than seven 137  
dollars and twenty-five cents of each fee credited to the 138  
genetics services fund shall be used to defray the costs of the 139  
programs authorized by section 3701.502 of the Revised Code. Not 140  
less than three dollars from each fee credited to the genetics 141  
services fund shall be used to defray costs of phenylketonuria 142  
programs. 143

(b) Not less than three dollars and seventy-five cents 144  
shall be deposited into the state treasury to the credit of the 145  
sickle cell fund, which is hereby created. Money credited to the 146  
sickle cell fund shall be used to defray costs of programs 147  
authorized by section 3701.131 of the Revised Code. 148

(2) In adopting rules under division (F) (1) of this 149  
section, the director shall not establish a fee that differs 150  
according to whether a screening is performed by the public 151  
health laboratory or by another laboratory selected by the 152  
director pursuant to division (E) (2) of this section. 153

**Section 2.** That existing section 3701.501 of the Revised 154  
Code is hereby repealed. 155