

As Introduced

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H. B. No. 397

Representatives Boggs, Butler

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

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