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

A BILL

То	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

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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

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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	1.4.0
sickle cell lund, which is heleby cleated. Money cleated to the	146
sickle cell fund shall be used to defray costs of programs	146
sickle cell fund shall be used to defray costs of programs authorized by section 3701.131 of the Revised Code.	147 148
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Code is hereby repealed.