

As Passed by the Senate

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Sub. S. B. No. 121

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Roberts, Brady, Mumper, Mead, Prentiss, Spada**

A B I L L

To amend sections 3701.23 and 3701.501 of the Revised Code to revise the law regarding required screening of newborn children for genetic, endocrine, and metabolic disorders.

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

Section 1. That sections 3701.23 and 3701.501 of the Revised Code be amended to read as follows:

Sec. 3701.23. (A) The director of health shall have charge of the laboratory authorized by section 3701.22 of the Revised Code. The director may employ an assistant for the laboratory who shall be a person skilled in chemistry and bacteriology, and receive such compensation as the director may allow. All expenses of such laboratory shall be paid from appropriations made for the department of health.

(B)~~(1)~~ The public health council, in accordance with Chapter 119. of the Revised Code, shall adopt, and may amend or rescind, rules establishing reasonable fees to be charged for services that the laboratory performs. The council need not prescribe fees to be charged in any case where the council believes that the charging of fees would significantly and adversely affect the public

health. ~~Except as provided in division (B)(2) of this section, all~~ 20
All fees collected for services that the laboratory performs shall 21
be deposited into the state treasury to the credit of the 22
"laboratory handling fee fund," which is hereby created for the 23
purpose of defraying expenses of operating the laboratory. 24

~~(2) The council, in accordance with division (B)(1) of this~~ 25
~~section, shall adopt a rule establishing a fee of not less than~~ 26
~~fourteen dollars for tests of newborn children conducted under~~ 27
~~section 3701.501 of the Revised Code. Of each such fee collected~~ 28
~~on or after the rule's effective date, not less than ten dollars~~ 29
~~and twenty-five cents shall be deposited into the state treasury~~ 30
~~to the credit of the genetics services fund, which is hereby~~ 31
~~created, and not less than three dollars and seventy-five cents~~ 32
~~shall be deposited into the state treasury to the credit of the~~ 33
~~sickle cell fund, which is hereby created. Not less than three~~ 34
~~dollars from each fee credited to the genetics services fund shall~~ 35
~~be used to defray costs of phenylketonuria programs. Not less than~~ 36
~~seven dollars and twenty-five cents of each fee credited to the~~ 37
~~genetics services fund shall be used to defray the costs of the~~ 38
~~programs authorized by section 3701.502 of the Revised Code. Money~~ 39
~~credited to the sickle cell fund shall be used to defray costs of~~ 40
~~programs authorized by section 3701.131 of the Revised Code.~~ 41
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Sec. 3701.501. (A) ~~The public health council shall adopt~~ 43
~~rules in accordance with Chapter 119. of the Revised Code for~~ 44
~~testing of~~ (1) Except as provided in division (A)(2) of this 45
section, all newborn children shall be screened for the presence 46
of phenylketonuria, homocystinuria, galactosemia, and 47
hypothyroidism. ~~The person designated in the rules shall cause a~~ 48
~~child to be tested in accordance with the rules. The rules may~~ 49
~~require tests for other~~ the genetic, endocrine, ~~or~~ and metabolic 50
~~disorders if the following conditions are met:~~ 51

~~(1) A determination is made by the public health council that the disorders cause disability if undiagnosed and untreated and are treatable.~~ 52
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~~(2) No additional blood samples or specimens are required to conduct the test.~~ 55
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~~All tests required by this section or by rules adopted by the public health council pursuant to this section shall be performed by the laboratory authorized by section 3701.22 of the Revised Code except that if the rules adopted by the public health council under this section provide that retesting of children with abnormal test results may be performed by laboratories other than that laboratory, retests may be performed by any laboratory approved by the director of health for that purpose.~~ 57
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~~Rules adopted by the public health council under this section shall prescribe a method for giving notice of the proposed tests and the results of the tests to the parents of the child. The rules shall also prescribe a method for giving notice of the proposed tests and the results of the tests to either the person who caused the child to be tested, employees designated by the rules of the hospital of birth, or the health commissioner for the health district where the birth occurred, whichever is appropriate as determined by the rules.~~ 65
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~~The rules also shall prescribe laboratory methods and other procedures for the detection of such genetic, endocrine, and metabolic disorders in newborn children, including procedures for retesting and referral of children with abnormal test results. With regard to tests for the presence of phenylketonuria, the laboratory methods and other procedures prescribed in the rules shall include any test that the council determines is effective for use in detecting the disorder in children who are less than forty-eight hours old.~~ 74
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(B) specified in rules, adopted pursuant to this section. 83

(2) Division (A)(1) of this section does not apply if the 84
parents of the child object thereto on the grounds that ~~such test~~ 85
the screening conflicts with their religious tenets and practices. 86

(B) There is hereby created the newborn screening advisory 87
council to advise the director of health regarding the screening 88
of newborn children for genetic, endocrine, and metabolic 89
disorders. The council shall engage in an ongoing review of the 90
newborn screening requirements established under this section and 91
shall provide recommendations and reports to the director as the 92
director requests and as the council considers necessary. The 93
director may assign other duties to the council, as the director 94
considers appropriate. 95

The director shall appoint the members of the council. In 96
making appointments, the director shall select individuals and 97
representatives of entities with interest and expertise in newborn 98
screening, including such individuals and entities as health care 99
professionals, hospitals, children's hospitals, regional genetic 100
centers, regional sickle cell centers, newborn screening 101
coordinators, and members of the public. 102

The department of health shall provide meeting space, staff 103
services, and other technical assistance required by the council 104
in carrying out its duties. Members of the council shall serve 105
without compensation, but shall be reimbursed for their actual and 106
necessary expenses incurred in attending meetings of the council 107
or performing assignments for the council. 108

The council is not subject to sections 101.82 to 101.87 of 109
the Revised Code. 110

(C)(1) The director of health shall adopt rules in accordance 111
with Chapter 119. of the Revised Code specifying the disorders for 112
which each newborn child must be screened. 113

(2) The newborn screening advisory council shall evaluate genetic, metabolic, and endocrine disorders to assist the director in determining which disorders should be included in the screenings required under this section. In determining whether a disorder should be included, the council shall consider all of the following: 114 115 116 117 118 119

(a) The disorder's incidence, mortality, and morbidity; 120

(b) Whether the disorder causes disability if diagnosis, treatment, and early intervention are delayed; 121 122

(c) The potential for successful treatment of the disorder; 123

(d) The expected benefits to children and society in relation to the risks and costs associated with screening for the disorder; 124 125 126

(e) Whether a screening for the disorder can be conducted without taking an additional blood sample or specimen. 127 128

(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. If the director agrees with a recommendation made by the council, the director shall adopt rules that correspond with the recommendation. 129 130 131 132 133 134 135

(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: 137 138 139 140

(1) Causing rescreenings to be performed when initial screenings have abnormal results; 141 142

(2) Designating the person or persons who will be responsible 143

for causing screenings and rescreenings to be performed; 144

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(3) Giving to the parents of a child notice of the required 146

initial screening and the possibility that rescreenings may be 147

necessary; 148

(4) Communicating to the parents of a child the results of 149

the child's screening and any rescreenings that are performed; 150

(5) Giving notice of the results of an initial screening and 151

any rescreenings to the person who caused the child to be screened 152

or rescreened, or to another person or government entity when the 153

person who caused the child to be screened or rescreened cannot be 154

contacted; 155

(6) Referring children who receive abnormal screening or 156

rescreening results to providers of follow-up services, including 157

the services made available through funds disbursed under division 158

(F) of this section. 159

(E)(1) Except as provided in divisions (E)(2) and (3) of this 160

section, all newborn screenings required by this section shall be 161

performed by the laboratory authorized under section 3701.22 of 162

the Revised Code. 163

(2) If the director determines that the laboratory authorized 164

under section 3701.22 of the Revised Code is unable to perform 165

screenings for all of the disorders specified in the rules adopted 166

under division (C) of this section, the director shall select 167

another laboratory to perform the screenings. The director shall 168

select the laboratory by issuing a request for proposals. The 169

director may accept proposals submitted by laboratories located 170

outside this state. At the conclusion of the selection process, 171

the director shall enter into a written contract with the selected 172

laboratory. If the director determines that the laboratory is not 173

complying with the terms of the contract, the director shall 174

immediately terminate the contract and another laboratory shall be
selected and contracted with in the same manner.

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(3) Any rescreening caused to be performed pursuant to this
section may be performed by the laboratory authorized by section
3701.22 of the Revised Code or one or more other laboratories
designated by the director. Any laboratory the director considers
qualified to perform rescreenings may be designated, including a
laboratory located outside this state. If more than one laboratory
is designated, the person responsible for causing a rescreening to
be performed is also responsible for selecting the laboratory to
be used.

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

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

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

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(2) In adopting rules under division (F)(1) of this section,

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the director shall not establish a fee that differs according to 207
whether a screening is performed by the laboratory authorized 208
under section 3701.22 of the Revised Code or by another laboratory 209
selected by the director pursuant to division (E)(2) of this 210
section. 211

Section 2. That existing sections 3701.23 and 3701.501 of the 212
Revised Code are hereby repealed. 213