

## As Introduced

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S. B. No. 121

SENATOR Blessing

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### A B I L L

To amend sections 3701.23, 3701.501, and 3701.502 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, 3701.501, and 3701.502 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~~

In the case of newborn screenings conducted pursuant to rules adopted under section 3701.501 of the Revised Code, the fee shall be in addition to the initial fee established under section 3701.502 of the Revised Code.

Except as provided in division (B)(2)(A) of this section 3701.502 of the Revised Code, all fees collected for services that the laboratory performs shall be deposited into the state treasury to the credit of the "laboratory handling fee fund," which is hereby created for the purpose of defraying expenses of operating the laboratory.

~~(2) The council, in accordance with division (B)(1) of this section, shall adopt a rule establishing a fee of not less than fourteen dollars for tests of newborn children conducted under section 3701.501 of the Revised Code. Of each such fee collected on or after the rule's effective date, not less than ten dollars and twenty-five cents shall be deposited into the state treasury to the credit of the genetics services fund, which is hereby created, and 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. Not less than three dollars from each fee credited to the genetics services fund shall be used to defray costs of phenylketonuria programs. 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. Money credited to the sickle cell fund shall be used to defray costs of programs authorized by section 3701.131 of the Revised Code.~~

**Sec. 3701.501.** (A) As used in this section and section 3701.502 of the Revised Code:

(1) "CLIA certified laboratory" means a laboratory that has a

valid certificate to perform examination of materials derived from  
the human body for the purpose of providing information for the  
diagnosis, prevention, or treatment of any disease issued pursuant  
to the "Clinical Laboratories Improvement Act (CLIA)," 81 Stat.  
536 (1967), 42 U.S.C.A. 263a, as amended.

(2) "Screening" means a process by which an individual  
undergoes a procedure to indicate whether the individual is at a  
greater or lesser risk of having a specific condition.

(B) The public health council shall adopt rules in accordance  
with Chapter 119. of the Revised Code for testing screening of all  
newborn children for the presence of ~~phenylketonuria,~~  
~~homocystinuria, galactosemia, and hypothyroidism.~~ The person  
~~designated in the rules shall cause a child to be tested in~~  
~~accordance with the rules. The rules may require tests for other~~  
~~genetic, endocrine, or metabolic disorders if the following~~  
~~conditions are met. The rules shall identify the disorders for~~  
~~which screening must be conducted; prescribe laboratory methods~~  
~~and other procedures for the detection of those disorders,~~  
~~including procedures for rescreening and referral of children with~~  
~~abnormal screening results; and designate the person responsible~~  
~~for causing the screening to be conducted.~~

In identifying the disorders for which screening must be  
conducted, the public health council shall consider the following  
criteria:

(1) ~~A determination is made by the public health council that~~  
~~the disorders cause~~ Whether the disorder causes disability if  
~~undiagnosed and untreated and are treatable. diagnosis, treatment,~~  
~~and early intervention are delayed;~~

(2) ~~No additional blood samples or specimens are required to~~  
~~conduct the test~~ Characteristics of the disorder, including  
incidence, morbidity, and mortality;

<u>(3) Potential for successful treatment;</u>	83
<u>(4) The specimen type required to conduct a screening;</u>	84
<u>(5) Characteristics of the screening, including sensitivity,</u>	85
<u>specificity, feasibility for mass screening, and cost;</u>	86
<u>(6) Expected benefits to children and society in relation to</u>	87
<u>the risks and costs associated with screening for the disorder.</u>	88
<u>(C) All tests screenings and any rescreenings required by</u>	89
this section or by rules adopted by the public health council	90
pursuant to this section shall be performed by the laboratory	91
authorized by section 3701.22 of the Revised Code <del>except that if</del>	92
<del>the rules adopted by the public health council under this section</del>	93
<del>provide that retesting of children with abnormal test results may</del>	94
<del>be performed by laboratories other than that laboratory, retests</del>	95
<del>may be performed by any laboratory approved by the director of</del>	96
<del>health for that purpose or a CLIA certified laboratory.</del>	97
<u>(D)(1) Rules adopted by the public health council under this</u>	98
section shall prescribe a method for giving notice of the proposed	99
<del>tests screenings</del> and the results of the <del>tests screenings</del> to the	100
parents of the child. <del>The</del>	101
<u>(2) The rules shall also prescribe a method for giving notice</u>	102
of the proposed <del>tests screenings</del> and the results of the <del>tests</del>	103
<del>screenings</del> to <del>either</del> the person who caused the child to be <del>tested</del>	104
<del>screened</del> , employees designated by the rules of the hospital <del>of or</del>	105
<del>other facility at which the birth occurred, a person or government</del>	106
<del>entity responsible for providing medical or nursing follow-up care</del>	107
<del>to the child</del> , or the health commissioner for the health district	108
where the birth occurred, whichever is appropriate as determined	109
by the rules. <u>Parental consent is not necessary for giving notice</u>	110
<u>of screening results to persons or government entities under</u>	111
<u>division (D)(2) of this section.</u>	112
<del>The rules also shall prescribe laboratory methods and other</del>	113

~~procedures for the detection of such genetic, endocrine, and 114  
metabolic disorders in newborn children, including procedures for 115  
retesting and referral of children with abnormal test results. 116  
With regard to tests for the presence of phenylketonuria, the 117  
laboratory methods and other procedures prescribed in the rules 118  
shall include any test that the council determines is effective 119  
for use in detecting the disorder in children who are less than 120  
forty-eight hours old. 121~~

~~(B) Division (A) of this section does 122~~

~~(E) The rules of the public health council adopted under this 123  
section do not apply to a child if the parents of the child object 124  
thereto to a screening on the grounds that such test the screening 125  
conflicts with their religious tenets and practices. 126~~

**Sec. 3701.502.** ~~(A) The public health council shall adopt 127  
rules establishing an initial fee of not less than fourteen 128  
dollars for screenings of newborn children conducted pursuant to 129  
rules adopted under section 3701.501 of the Revised Code. Whether 130  
paid directly to the Ohio department of health or paid to a 131  
hospital, free standing birthing center, or person and transmitted 132  
to the department, the initial fee shall be disbursed as follows: 133~~

~~(1) Not less than ten dollars and twenty-five cents shall be 134  
deposited in the state treasury to the credit of the genetics 135  
services fund, which is hereby created. Not less than seven 136  
dollars and twenty-five cents of each fee credited to the genetics 137  
services fund shall be used to defray the costs of the programs 138  
authorized by division (C) of this section. Not less than three 139  
dollars from each fee credited to the genetics services fund shall 140  
be used to defray costs of phenylketonuria programs. 141~~

~~(2) Not less than three dollars and seventy-five cents shall 142  
be deposited into the state treasury to the credit of the sickle 143  
cell fund, which is hereby created. Money credited to the sickle 144~~

cell fund shall be used to defray costs of programs authorized by  
section 3701.131 of the Revised Code.

(B)(1) Any amount charged by the laboratory authorized by  
section 3701.22 of the Revised Code for screening a newborn child  
that exceeds the initial fee shall be deposited in the state  
treasury in accordance with division (B) of section 3701.23 of the  
Revised Code.

(2) Any amount charged by a CLIA certified laboratory for  
screening a newborn child that exceeds the initial fee shall be  
paid to the CLIA certified laboratory.

(C) The director of health shall do all of the following:

(A)(1) Encourage and assist in the development of programs of  
education, detection, and treatment of genetic diseases and  
provide for habilitation, rehabilitation, and counseling of  
persons possessing a genetic trait of, or afflicted with, genetic  
disease;

(B)(2) Advise, consult, cooperate with, and assist, by  
contract or otherwise, agencies of this state and the federal  
government, agencies of the governments of other states, agencies  
of political subdivisions of this state, and private  
organizations, corporations, and associations in the development  
and promotion of programs pertaining to the causes, detection, and  
treatment of genetic diseases, habilitation, rehabilitation, and  
counseling of persons possessing the trait of or afflicted with  
genetic disease;

(C)(3) Accept and administer grants from the federal  
government or other sources, public or private, for carrying out  
any of the functions enumerated in divisions (A)(C)(1) and (B)(2)  
of this section. All such moneys so received shall be deposited by  
the director in the state treasury and shall be kept in a separate  
fund by the treasurer of state. Except as otherwise provided in

section 3701.45 of the Revised Code, payments from the fund shall	176
be made pursuant to vouchers approved by the director.	177

<b>Section 2.</b> That existing sections 3701.23, 3701.501, and	178
3701.502 of the Revised Code are hereby repealed.	179