



Ohio Revised Code

Section 3701.501 Newborns screened for genetic, endocrine, and metabolic disorders.

Effective: September 29, 2015

Legislation: House Bill 64 - 131st General Assembly

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

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

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

(b) With respect to the screening for Krabbe disease described in division (C)(1)(b) of this section, if the parents of the child communicate their decision to forgo the screening.

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

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

The department of health shall provide meeting space, staff services, and other technical assistance required by the council in carrying out its duties. Members of the council shall serve without



compensation, but shall be reimbursed for their actual and necessary expenses incurred in attending meetings of the council or performing assignments for the council.

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

(C)(1)(a) Subject to division (C)(1)(b) of this section, the director of health shall adopt rules in accordance with Chapter 119. of the Revised Code specifying the disorders for which each newborn child must be screened.

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

(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:

- (a) The disorder's incidence, mortality, and morbidity;
- (b) Whether the disorder causes disability if diagnosis, treatment, and early intervention are delayed;
- (c) The potential for successful treatment of the disorder;
- (d) The expected benefits to children and society in relation to the risks and costs associated with screening for the disorder;
- (e) Whether a screening for the disorder can be conducted without taking an additional blood sample or specimen.

(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.

(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:

- (1) Causing rescreenings to be performed when initial screenings have abnormal results;
- (2) Designating the person or persons who will be responsible for causing screenings and rescreenings to be performed;
- (3) Giving to the parents of a child notice of the required initial screening and the possibility that rescreenings may be necessary;
- (4) Communicating to the parents of a child the results of the child's screening and any rescreenings that are performed;
- (5) Giving notice of the results of an initial screening and any rescreenings to the person who caused the child to be screened or rescreened, or to another person or government entity when the person who caused the child to be screened or rescreened cannot be contacted;
- (6) Referring children who receive abnormal screening or rescreening results to providers of follow-up services, including the services made available through funds disbursed under division (F) of this section.

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

(2) If the director determines that the public health laboratory is unable to perform screenings for all of the disorders specified in the rules adopted under division (C) of this section, the director shall



select another laboratory to perform the screenings. The director shall select the laboratory by issuing a request for proposals. The director may accept proposals submitted by laboratories located outside this state. At the conclusion of the selection process, the director shall enter into a written contract with the selected laboratory. If the director determines that the laboratory is not complying with the terms of the contract, the director shall immediately terminate the contract and another laboratory shall be selected and contracted with in the same manner.

(3) Any rescreening caused to be performed pursuant to this section may be performed by the public health laboratory 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.

(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:

(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.

(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.

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