



Ohio Revised Code

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

Effective: September 30, 2021

Legislation: House Bill 110

(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 any 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;

(c) If appropriate laboratory equipment is not available.

(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, all of the following apply:

(i) 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.

(ii) The director shall specify spinal muscular atrophy and X-linked adrenoleukodystrophy as disorders for which a newborn child who is born on or after the date that is two hundred forty days after the effective date of this amendment must be screened.

(iii) Not later than six months after receiving a recommendation as described in division (C)(3)(b) of this section, the director shall specify for screening a disorder recommended as described in division (C)(3)(b) of this section, with such screening to begin not later than one year after the date that the rule specifying the disorder for screening becomes effective.

(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;
 - (f) Whether the secretary of the United States department of health and human services has included the disorder in the federal recommended uniform screening panel.
- (3)(a) 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.
- (b) In the case of a disorder included within the federal recommended uniform screening panel, the council shall determine not later than six months after the date of the disorder's inclusion on the federal panel whether or not to recommend to the director that each newborn child be screened for the disorder. If the council recommends screening for the disorder, the council shall submit to the director as soon as practicable a recommendation for such screening.
 - (c) 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.



Ohio Revised Code

Section 3701.503 Testing newborns definitions.

Effective: September 10, 2012

Legislation: House Bill 487

As used in sections 3701.504 to 3701.509 of the Revised Code:

(A) "Parent" means either parent, unless the parents are separated or divorced or their marriage has been dissolved or annulled, in which case "parent" means the parent who is the residential parent and legal custodian.

(B) "Guardian" has the same meaning as in section 2111.01 of the Revised Code.

(C) "Custodian" means, except as used in division (A) of this section, a government agency or an individual, other than the parent or guardian, with legal or permanent custody of a child as defined in section 2151.011 of the Revised Code.

(D) "Hearing screening" means the identification of newborns and infants who may have a hearing impairment, through the use of a physiologic test.

(E) "Hearing evaluation" means evaluation through the use of audiological procedures by an audiologist or physician.

(F) "Hearing impairment" means a loss of hearing in one or both ears in the frequency region important for speech recognition and comprehension.

(G) "Newborn" means a child who is less than thirty days old.

(H) "Infant" means a child who is at least thirty days but less than twenty-four months old.

(I) "Freestanding birthing center" has the same meaning as in section 3702.141 of the Revised Code.

(J) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice



medicine and surgery or osteopathic medicine and surgery.

(K) "Audiologist" means an individual authorized under section 4753.07 of the Revised Code to practice audiology.

(L) "Hospital" means a hospital that has a maternity unit or newborn nursery.

(M) "Maternity unit" means any unit or place in a hospital where women are regularly received and provided care during all or part of the maternity cycle, except that "maternity unit" does not include an emergency department or similar place dedicated to providing emergency health care.

(N) "Board of health" means the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code.



Ohio Revised Code

Section 3701.504 Program to identify newborn and infant hearing impairment.

Effective: August 1, 2002

Legislation: House Bill 150 - 124th General Assembly

(A) The department of health shall establish and maintain a statewide hearing screening, tracking, and early intervention program to identify newborn and infant hearing impairment. The department shall also establish appropriate protocols for the treatment and follow-up care of newborns and infants with hearing impairment.

(B) In the case of a child born in a hospital or freestanding birthing center, both of the following apply:

(1) The program shall provide for a hearing screening of the newborn or infant before discharge, unless the newborn or infant is being transferred to another hospital.

(2) If the newborn or infant is transferred to another hospital, the program shall provide for a hearing screening of the newborn or infant when determined to be medically appropriate.

(C) The department of health shall ensure that the program established under this section is incorporated into early intervention activities of the department in compliance with the "Individuals with Disabilities Education Act," 20 U.S.C.A. 1400 et seq.

(D) The department of health may assist hospitals and freestanding birthing centers in acquiring hearing screening equipment by providing information on grant opportunities or loans, and, if funds are available, by mass purchasing equipment or establishing a grant system with department funds.

(E) The department of health shall administer the program established under this section pursuant to rules adopted under section 3701.508 of the Revised Code.



Ohio Revised Code

Section 3701.505 Hospitals and freestanding birthing centers duties concerning hearing screening.

Effective: August 1, 2002

Legislation: House Bill 150 - 124th General Assembly

(A)(1) Each hospital and each freestanding birthing center shall do all of the following:

(a) Conduct a hearing screening on each newborn or infant born in the hospital or center unless the newborn or infant is transferred to another hospital;

(b) Promptly notify the newborn's or infant's attending physician of the screening results;

(c) Notify the department of health of the screening results for each newborn or infant screened.

(2) A hearing screening conducted under this section shall be conducted under the direction of an audiologist or physician or in collaboration with a physician. Notwithstanding the licensure requirements of Chapter 4753. of the Revised Code, a screening may be conducted by a person who is not licensed under that chapter.

(3) Each hospital and freestanding birthing center shall take the actions required by divisions (A)(1) and (2) of this section in accordance with the rules adopted under section 3701.508 of the Revised Code. A hospital or freestanding birthing center may commence taking these actions at any time after the effective date of the rules but not later than June 30, 2004, unless an extension is granted. The director may grant an extension to delay for up to one year after June 30, 2004, the requirement of compliance with the rules if the hospital or freestanding birthing center requesting the extension demonstrates justifiable cause for the extension. Justifiable cause may include having ordered but not yet received hearing screening equipment, ongoing efforts to obtain financing for the equipment, or any other cause accepted by the director.

(B) Any hospital or freestanding birthing center providing a hearing screening in accordance with division (A) of this section shall be reimbursed by the department of health at a rate determined by the director of health, if both of the following are the case:



(1) The screening is performed before the newborn or infant is discharged from the hospital or freestanding birthing center.

(2) The parent, guardian, or custodian is financially unable to pay for the hearing screening and the hospital or freestanding birthing center is not reimbursed by a third-party payer as determined pursuant to rules adopted under section 3701.508 of the Revised Code.

(C) A hospital, clinic, or other health care facility at which a hearing evaluation is performed on a newborn or infant shall report the results of the evaluation to the attending physician of the newborn or infant.



Ohio Revised Code

Section 3701.506 Preparing and distributing of information concerning hearing loss.

Effective: August 1, 2002

Legislation: House Bill 150 - 124th General Assembly

The department of health shall prepare and distribute to all hospitals and freestanding birthing centers required to provide hearing screenings under the program established under section 3701.504 of the Revised Code and each board of health, information describing factors or conditions of hearing loss and the effect of such a loss on an infant or child's language development, and information on the importance of hearing screening, hearing evaluation, early intervention, and follow-up care for newborns and infants. This information shall be updated as the department determines necessary.

Each hospital or freestanding birthing center shall provide the parent, guardian, or custodian of each newborn or infant born in the hospital or freestanding birthing center with the information prepared by the department pursuant to this section.

Each board of health shall provide the parent, guardian, or custodian of each newborn or infant born in the area served by the board who is not born in a hospital or freestanding birthing center with the information prepared by the department pursuant to this section.



Ohio Revised Code

Section 3701.507 Infant hearing screening subcommittee.

Effective: September 29, 2013

Legislation: House Bill 59 - 130th General Assembly

(A) To assist in implementing sections 3701.503 to 3701.509 of the Revised Code, the medically handicapped children's medical advisory council created in section 3701.025 of the Revised Code shall appoint a permanent infant hearing screening subcommittee. The subcommittee shall consist of the following members:

- (1) One otolaryngologist;
- (2) One neonatologist;
- (3) One pediatrician;
- (4) One neurologist;
- (5) One hospital administrator;
- (6) Two or more audiologists who are experienced in infant hearing screening and evaluation;
- (7) One speech-language pathologist licensed under section 4753.07 of the Revised Code;
- (8) Two persons who are each a parent of a hearing-impaired child;
- (9) One geneticist;
- (10) One epidemiologist;
- (11) One adult who is deaf or hearing impaired;
- (12) One representative from an organization for the deaf or hearing impaired;



- (13) One family advocate;
 - (14) One nurse from a well-baby neonatal nursery;
 - (15) One nurse from a special care neonatal nursery;
 - (16) One teacher of the deaf who works with infants and toddlers;
 - (17) One representative of the health insurance industry;
 - (18) One representative of the bureau for children with medical handicaps;
 - (19) One representative of the department of education;
 - (20) One representative of the department of medicaid;
 - (21) Any other person the advisory council appoints.
- (B) The infant hearing subcommittee shall:
- (1) Consult with the director of health regarding the administration of sections 3701.503 to 3701.509 of the Revised Code;
 - (2) Advise and make recommendations regarding proposed rules prior to their adoption by the director under section 3701.508 of the Revised Code;
 - (3) Consult with the director of health and advise and make recommendations regarding program development and implementation under sections 3701.503 to 3701.509 of the Revised Code, including all of the following:
 - (a) Establishment under section 3701.504 of the Revised Code of the statewide hearing screening, tracking, and early intervention program to identify newborn and infant hearing impairment;



- (b) Identification of locations where hearing evaluations may be conducted;
- (c) Recommendations for methods and techniques of hearing screening and hearing evaluation;
- (d) Referral, data recording and compilation, and procedures to encourage follow-up hearing care;
- (e) Maintenance of a register of newborns and infants who do not pass the hearing screening;
- (f) Preparation of the information required by section 3701.506 of the Revised Code.



Ohio Revised Code

Section 3701.508 Statewide hearing screening, tracking, and early intervention program rules.

Effective: September 10, 2012

Legislation: House Bill 487 - 129th General Assembly

(A) The director of health shall adopt rules governing the statewide hearing screening, tracking, and early intervention program established under section 3701.504 of the Revised Code, including rules that do all of the following:

(1) Specify how hospitals and freestanding birthing centers are to comply with the requirements of section 3701.505 of the Revised Code, including methods to be used for hearing screening, except that with regard to the physiologic equipment to be used for hearing screening, the rules may require only that the equipment be capable of giving reliable results and may not specify particular equipment or a particular type of equipment;

(2) Provide that no newborn or infant shall be required to undergo a hearing screening if the parent, guardian, or custodian of the newborn or infant objects on the grounds that the screening conflicts with the parent's, guardian's, or custodian's religious tenets and practices;

(3) Provide for situations in which the parent, guardian, or custodian of a newborn or infant objects to a hearing screening for reasons other than religious tenets and practices;

(4) Specify how the department of health will determine whether a person is financially unable to pay for a hearing screening and define "third-party payer" for the purpose of reimbursement of hearing screening by the department under section 3701.505 of the Revised Code;

(5) Specify an inexpensive and efficient format and procedures for the submission of hearing screening information from hospitals and freestanding birthing centers to the department of health;

(6) Specify a procedure whereby the department may conduct timely reviews of hearing screening information submissions for purposes of quality assurance, training, and disease prevention and control;



(7) Specify any additional information that hospitals and freestanding birthing centers are to provide to the medically handicapped children's medical advisory council's infant hearing screening subcommittee under section 3701.509 of the Revised Code.

(B) In addition to the rules adopted under division (A) of this section, the director shall adopt rules that specify the training that must be completed by persons who will conduct hearing screenings. In adopting these rules, the director shall consider incorporating cost-saving training methods, including computer-assisted learning and on-site training. Neither the rules nor the director of health may establish a minimum educational level for persons conducting hearing screenings.

(C) All rules adopted under this section shall be adopted in accordance with Chapter 119. of the Revised Code and shall be adopted so as to take effect not later than six months after August 1, 2002.



Ohio Revised Code

Section 3701.509 Analyzing and interpreting hearing screening information.

Effective: September 10, 2012

Legislation: House Bill 487 - 129th General Assembly

(A) The department of health shall develop a mechanism to analyze and interpret the hearing screening information to be reported under division (B) of this section. The department shall notify all hospitals and freestanding birthing centers subject to the reporting requirements of the date the department anticipates that the mechanism will be complete. After the mechanism is complete, the department shall notify each hospital and freestanding birthing center subject to the reporting requirement of the date by which the hospital or center must submit its first report.

(B) Subject to division (A) of this section and in accordance with rules adopted by the director of health under section 3701.508 of the Revised Code, each hospital and freestanding birthing center that has conducted a hearing screening required by section 3701.505 of the Revised Code shall provide to the department of health for use by the medically handicapped children's medical advisory council's infant hearing screening subcommittee information specifying all of the following:

- (1) The number of newborns born in the hospital or freestanding birthing center and the number of newborns and infants not screened because they were transferred to another hospital;
- (2) The number of newborns and infants referred to the hospital or freestanding birthing center for a hearing screening and the number of those newborns and infants who received a hearing screening;
- (3) The number of newborns and infants who did not pass the hearing screenings conducted by the hospital or freestanding birthing center;
- (4) Any other information concerning the program established under section 3701.504 of the Revised Code.

(C) The department of health shall conduct a timely review of the information submitted by hospitals and freestanding birthing centers in accordance with rules adopted by the director under



section 3701.508 of the Revised Code.

(D) The infant hearing screening subcommittee, with the support of the department of health, shall compile and summarize the information submitted to the department by hospitals and freestanding birthing centers under division (B) of this section. Beginning with the first year after the mechanism developed under division (A) of this section is complete, the subcommittee shall annually prepare and transmit a report to the director of health, the speaker of the house of representatives, and the president of the senate. The council shall make the report available to the public.

(E) The department and all members of the subcommittee shall maintain the confidentiality of patient-identifying information submitted under division (B) of this section and section 3701.505 of the Revised Code. The information is not a public record under section 149.43 of the Revised Code, except to the extent that the information is used in preparing reports under this section.

Nothing in this division prohibits the department from providing patient-identifying information to other entities as it considers necessary to implement the statewide tracking and early intervention components of the program established under section 3701.504 of the Revised Code. Any entity that receives patient-identifying information from the department shall maintain the confidentiality of the information.