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25-4-803. Rules and regulations. (1) The state board of health shall promulgate rules and regulations concerning the obtaining of samples or specimens from newborn infants required for the tests prescribed by the state board of health for the handling and delivery of the same and for the testing and examination thereof to detect phenylketonuria or other metabolic disorders found likely to cause mental retardation.

(2) The department of public health and environment shall furnish all physicians, public health nurses, hospitals, maternity homes, county departments of social services, and the state department of human services available medical information concerning the nature and effects of phenylketonuria and other metabolic disorders and defects found likely to cause mental retardation.

Source: L. 65: p. 722, § 3. C.R.S. 1963: § 66-27-3. L. 94: (2) amended, p. 2766, § 447, effective July 1.

Cross references: For the legislative declaration contained in the 1994 act amending subsection (2), see section 1 of chapter 345, Session Laws of Colorado 1994.

25-4-804. Exceptions. Nothing in the provisions of this part 8 shall be construed to require the testing or medical treatment for the minor child of any person who is a member of a well-recognized church or religious denomination and whose religious convictions in accordance with the tenets or principles of his church or religious denomination are against medical treatment for disease or physical defects.

25-4-1004. Newborn screening.

(1) (a) Repealed.

(b) On or after April 1, 1989, all infants born in the state of Colorado shall be tested for the following conditions: Phenylketonuria, hypothyroidism, abnormal hemoglobins, galactosemia, cystic fibrosis, biotinidase deficiency, and such other conditions as the board of health may determine meet the criteria set forth in paragraph (c) of this subsection (1). Appropriate specimens for such testing shall be forwarded by the hospital in which the child is born to the laboratory operated or designated by the department of public health and environment for such

purposes. The physician, nurse, midwife, or other health professional attending a birth outside a hospital shall be responsible for the collection and forwarding of such specimens. The results of the testing shall be forwarded directly to the physician or other primary health care provider for the provision of such information to the parent or parents of the child. The results of any testing or follow-up testing pursuant to section 25-4-1004.5 may be sent to the immunization tracking system authorized by section 25-4-2403 and accessed by the physician or other primary health care provider. The state board of health may discontinue testing for any condition listed in this paragraph (b) if, upon consideration of criteria set forth in paragraph (c) of this subsection (1), the board finds that the public health is better served by not testing infants for that condition.

(c) The board of health shall use the following criteria to determine whether or not to test infants for conditions which are not specifically enumerated in this subsection (1):

(I) The condition for which the test is designed presents a significant danger to the health of the infant or his family and is amenable to treatment;

(II) The incidence of the condition is sufficiently high to warrant screening;

(III) The test meets commonly accepted clinical standards of reliability, as demonstrated through research or use in another state or jurisdiction; and

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(IV) The cost-benefit consequences of screening are acceptable within the context of the total newborn screening program.

(2) The executive director of the department of public health and environment shall assess a fee which is sufficient to cover the costs of such testing and to accomplish the other purposes of this part 10. Hospitals shall assess a reasonable fee to be charged the parent or parents of the infant to cover the costs of handling the specimens, the reimbursement of laboratory costs, and the costs of providing other services necessary to implement the purposes of this part 10.

Source: L. 81: Entire part added, p. 1302, § 1, effective July 1. L. 83: (2) amended, p. 1070, § 1, effective May 20. L. 87: (1) amended, p. 1128, § 1, effective July 1. L. 88: (1) amended, p. 1009, § 1, effective July 1. L. 91: (1) amended, p. 949, § 17, effective May 6. L. 94: (1)(b) and (2) amended, p. 2769, § 456, effective July 1. L. 96: (1)(b) amended, p. 1107, § 1, effective July 1. L. 2007: (1)(b) amended, p. 654, § 2, effective April 26.

Editor's note: Subsection (1)(a)(II) provided for the repeal of subsection (1)(a), effective April 1, 1989. (See L. 88, p. 1009.)

Cross references: For the legislative declaration contained in the 1994 act amending subsections (1)(b) and (2), see section 1 of chapter 345, Session Laws of Colorado 1994.

25-4-1004.3. Newborn heart defect screening - pulse oximetry - rules - definition. (1) (a) On and after January 1, 2016, a birthing facility that is below seven thousand feet of elevation shall test all infants born in the facility for critical congenital heart defects using pulse oximetry.

(b) Upon receipt of the confirmation of the appropriate algorithm for the pulse oximetry reading from the newborn screening committee, the newborn screening committee shall evaluate whether pulse oximetry testing in birthing facilities at or above seven thousand feet elevation meets the criteria in section 25-4-1004. Upon confirmation from the committee that the criteria have been met, the state board of health shall promulgate rules to ensure that all newborns born at or above seven thousand feet elevation are screened for critical congenital heart defects.

(c) The critical congenital heart defect screening using pulse oximetry must be performed on every newborn prior to the newborn's release from the birthing facility.

(2) Each birthing facility shall report the results of the pulse oximetry screenings to the department of public health and environment. The state board of health may promulgate rules for the implementation of this section.

(3) As used in this section, a "birthing facility" means a general hospital or birthing center licensed or certified pursuant to section 25-1.5-103 and that provides birthing and newborn care services.

Source: L. 2015: Entire section added, (HB 15-1281), ch. 241, p. 893, § 2, effective August 5. L. 2016: (1)(b) amended, (SB 16-189), ch. 210, p. 770, § 61, effective June 6.

Cross references: For the legislative declaration in HB 15-1281, see section 1 of chapter 241, Session Laws of Colorado 2015.

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25-4-1004.5. Follow-up testing and treatment - second screening - legislative declaration - fee - rules. (1) The general assembly finds that:

(a) Newborn screening authorized by section 25-4-1004 is provided for every newborn in the state;

(b) Newborn testing is designed to identify metabolic disorders that cause mental retardation and other health problems unless they are diagnosed and treated early in life;

(c) In order to ensure that children with metabolic disorders are able to lead as normal a life as possible and to minimize long-term health care costs for such children, it is necessary to provide centralized follow-up testing and treatment services;

(d) For over twenty-five years the follow-up testing and treatment services were provided by a federal grant that was discontinued June 30, 1993. Since that time, follow-up testing and

treatment services have been limited. If alternative sources of funding are not provided, those services will be eliminated.

(e) A nominal increase of the fee on newborn screening to cover the costs of providing follow-up and referral services would allow for those services to be continued;

(f) Over the past ten years, many children with serious health conditions have received timely diagnosis and treatment as a result of the newborn screening required by this part 10. Such screening has averted the possibility of life-long institutionalization of some children and substantial related health care costs. The general assembly further finds, however, that many infants who are screened early in life may exhibit false or inaccurate results on certain newborn screening tests. The general assembly therefore finds and declares that subsequent newborn screening will provide more accurate and reliable test results for the timely and effective diagnosis and treatment of certain health conditions in newborn infants and the best interests of children in Colorado will be served by a new screening program that routinely tests all newborns twice.

(2) (a) Repealed.

(b) On and after July 1, 1994, the executive director of the department of public health and environment shall increase the newborn screening fee as provided in section 25-4-1004 (2) so that the fee is sufficient to include the costs of providing follow-up and referral services to families with a newborn whose test results under a newborn screening indicate a metabolic disorder. Follow-up services include comprehensive diagnostic testing. The increase shall not exceed five dollars; except that it may be adjusted annually to reflect any change in the Denver-Boulder consumer price index. Any fees collected shall be subject to the provisions of section 25-4-1006.

(3) (a) On and after July 1, 1996, all infants born in the state of Colorado who receive newborn screening pursuant to section 25-4-1004 (1) shall have a second specimen taken to screen for the following conditions:

- (I) Phenylketonuria;
- (II) Hypothyroidism;
- (III) Galactosemia;
- (IV) Cystic fibrosis; and
- (V) Such other conditions as the state board of health may determine meet the criteria set

forth in section 25-4-1004 (1)(c) and require a second screening for accurate test results.

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(b) The executive director of the department of public health and environment is authorized to promulgate rules, regulations, and standards for the implementation of the second specimen testing specified in this subsection (3), including but not limited to the following:

- (I) Identification of those conditions for which a second specimen shall be required;
- (II) The age of the infant at which the second screening may be administered;
- (III) The method by which the parent or parents of a newborn shall be advised of the necessity for a second specimen test;
- (IV) The procedure to be followed in administering the second specimen test;
- (V) Any exceptions to the necessity for a second specimen test and the procedures to be

followed in such cases; and

- (VI) The standards of supervision and quality control that shall apply to second

specimen testing.

(c) On and after July 1, 1996, the executive director of the department of public health

and environment may adjust the newborn screening fee set forth in section 25-4-1004 (2) so that the fee is sufficient to cover the costs associated with the second screening described in this subsection (3). Any increase shall be in addition to the fee described in subsection (2) of this section and shall not initially exceed five dollars and seventy-five cents but may be adjusted annually to reflect any actual cost increase associated with the administration of the second screening. Any fees collected pursuant to this paragraph (c) shall be subject to the provisions of section 25-4-1006.

(4) The provisions of section 25-4-1003 (2) shall apply to second newborn screenings.

Source: L. 94: Entire section added, p. 833, § 1, effective April 28. L. 96: (1)(f), (3), and (4) added, p. 1108, §§ 2, 3, effective July 1.

Editor's note: Subsection (2)(a)(II) provided for the repeal of subsection (2)(a), effective July 1, 1994. (See L. 94, p. 833.)

25-4-1004.7. Newborn hearing screening - legislative declaration - advisory committee - report - rules. (1) (a) The general assembly finds, determines, and declares:

(I) That hearing loss occurs in newborn infants more frequently than any other health condition for which newborn infant screening is required;

(II) That eighty percent of the language ability of a child is established by the time the child is eighteen months of age and that hearing is vitally important to the healthy development of such language skills;

(III) That early detection of hearing loss in a child and early intervention and treatment has been demonstrated to be highly effective in facilitating a child's healthy development in a manner consistent with the child's age and cognitive ability;

(IV) That children with hearing loss who do not receive such early intervention and treatment frequently require special educational services and that such services are publicly funded for the vast majority of children with hearing needs in the state;

(V) That appropriate testing and identification of newborn infants with hearing loss will facilitate early intervention and treatment and may therefore serve the public purposes of promoting the healthy development of children and reducing public expenditure; and

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(VI) That consumers should be entitled to know whether the hospital at which they choose to deliver their infant provides newborn hearing screening.

(b) For these reasons the general assembly hereby determines that it would be beneficial and in the best interests of the development of the children of the state of Colorado that newborn infants' hearing be screened.

(2) (a) (I) There is hereby established an advisory committee on hearing in newborn infants for the purpose of collecting the informational data specified in paragraph (b) of subsection (3) of this section, and for the purpose of providing recommendations to hospitals, other health care institutions, the department of public health and environment, and the public concerning, but not necessarily limited to, the following:

(A) Appropriate methodologies to be implemented for hearing screening of newborn infants, which methodologies shall be objective and physiologically based and which shall not include a requirement that the initial newborn hearing screening be performed by an audiologist;

(B) The number of births sufficient to qualify a hospital or health institution to arrange otherwise for hearing screenings; and

(C) Guidelines for reporting and the means to assure that identified children receive referral for appropriate follow-up services.

(II) The advisory committee on hearing in newborn infants shall consist of at least seven members who shall be appointed by the executive director of the department of public health and environment. Members appointed to the committee shall have training, experience, or interest in the area of hearing conditions in children.

(III) The members of the advisory committee on hearing in newborn infants shall serve without compensation.

(IV) Repealed.

(b) Repealed.

(3) (a) It is the intent of the general assembly that newborn hearing screening be

conducted on no fewer than ninety-five percent of the infants born in hospitals, using procedures recommended by the advisory committee on hearing in newborn infants, created in subsection (2) of this section. Toward that end, every licensed or certified hospital shall educate the parents of infants born in such hospitals of the importance of screening the hearing of newborn infants and follow-up care. Education shall not be considered a substitute for the hearing screening described in this section. Every licensed or certified hospital shall report annually to the advisory committee concerning the following:

- (I) The number of infants born in the hospital;
 - (II) The number of infants screened;
 - (III) The number of infants who passed the screening, if administered; and
 - (IV) The number of infants who did not pass the screening, if administered.
- (b) The advisory committee on hearing in newborn infants shall determine which

hospitals or other health care institutions in the state of Colorado are administering hearing screening to newborn infants on a voluntary basis and the number of infants screened.

(I) to (IV) Repealed.

(c) Repealed.

(4) (a) If the number of infants screened falls below eighty-five percent, the board of

health shall promulgate rules requiring hearing screening of newborn infants pursuant to section 24-4-103, C.R.S., of the "State Administrative Procedure Act".

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(b) Such rules, if promulgated, shall address those hospitals with a low volume of births, as determined by the state board of health based upon recommendations by the advisory committee on hearing in newborn infants, which may arrange otherwise for newborn infant hearing screening.

(5) A physician, nurse, midwife, or other health professional attending a birth outside a hospital or institution shall provide information, as established by the department, to parents regarding places where the parents may have their infants' hearing screened and the importance of such screening.

(6) The department shall encourage the cooperation of county, district, and municipal public health agencies, health care clinics, school districts, and any other appropriate resources to promote the screening of newborn infants' hearing for those infants born outside a hospital or institution.

Source: L. 97: Entire section added, p. 1118, § 1, effective July 1. L. 2005: (2)(a)(I), (2)(b), (3)(a), IP(3)(b), and (4)(a) amended and (2)(a)(IV), (3)(b)(I) to (3)(b)(IV), and (3)(c) repealed, p. 252, §§ 3, 4, 5, effective July 1. L. 2008: (2)(b) amended, p. 1906, § 100, effective August 5. L. 2010: (6) amended, (HB 10-1422), ch. 419, p. 2096, § 102, effective August 11. L. 2013: (2)(b) repealed, (SB 13-163), ch. 79, p. 252, § 1, effective July 1.

25-4-1005. Exceptions. Nothing in the provisions of this part 10 shall be construed to require the testing or medical treatment for the minor child of any person or of any person who is a member of a well-recognized church or religious denomination and whose religious convictions in accordance with the tenets or principles of his church or religious denomination are against medical treatment for disease or physical defects or has a personal objection to the administration of such tests or treatment.