A BILL FOR AN ACT

CONCERNING MODIFICATIONS TO THE NEWBORN SCREENING PROGRAM

ADMINISTERED BY THE DEPARTMENT OF PUBLIC HEALTH AND
ENVIRONMENT.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov.)

The bill updates the current newborn screening program to require more timely newborn hearing screenings. The department of public health and environment is authorized to assess a fee for newborn screening and necessary follow-up services. The bill creates the newborn hearing screening cash fund for the purpose of covering the costs of the program.
Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, repeal part 8 of article 4 of title 25.

SECTION 2. In Colorado Revised Statutes, amend 25-4-1002 as follows:

25-4-1002. Legislative declaration. (1) The general assembly hereby finds and declares that:

(a) Recent newborn screening innovations are considered among the greatest public health achievements of the twenty-first century;

(b) Scientific research has demonstrated that newborn screening not only saves lives and improves developmental outcomes but also contributes to cost savings for families, health care systems, and the state;

(c) Newborn screening includes conditions for which diagnosis and treatment must be implemented in a timely manner in order to achieve maximum benefit for the child;

(d) Newborn screening is an appropriate public health function to provide necessary educational services to health care providers, families, and communities so that appropriate resources and information are available;

(e) Newborn screening is a public health function that identifies newborns at risk of certain conditions or hearing loss, as well as newborns who do not receive screening, and appropriately connects them to care;

(f) An effective newborn screening program is dependent
UPON A STRONG SYSTEM OF EDUCATION AND COORDINATION AMONG
PRIMARY CARE PROVIDERS, HOSPITALS, SPECIALTY CARE PROVIDERS,
PATIENT AND FAMILY SUPPORT ORGANIZATIONS, PUBLIC HEALTH
LABORATORY STAFF, AND PUBLIC HEALTH PROFESSIONALS;

(a) (g) State policy regarding newborn screening and genetic
counseling and education should be made with full public knowledge, in
light of expert opinion, and should be constantly reviewed to consider
changing medical knowledge and ensure full public protection;

(b) (h) Participation of persons in genetic counseling programs in
this state should be wholly voluntary and that all information obtained
from persons involved in such programs or in newborn screening
programs in the state should be held strictly confidential.

(i) HEARING LOSS OCCURS IN NEWBORN INFANTS MORE
FREQUENTLY THAN ANY OTHER HEALTH CONDITION FOR WHICH NEWBORN
INFANT SCREENING IS REQUIRED;

(j) EIGHTY PERCENT OF THE LANGUAGE ABILITY OF A CHILD IS
ESTABLISHED BY THE TIME THE CHILD IS EIGHTEEN MONTHS OF AGE, AND
IT IS VITALLY IMPORTANT TO SUPPORT THE HEALTHY DEVELOPMENT OF
LANGUAGE SKILLS;

(k) EARLY DETECTION, EARLY INTERVENTION, AND TREATMENT OF
HEARING LOSS IN A CHILD ARE HIGHLY EFFECTIVE IN FACILITATING A
CHILD’S HEALTHY DEVELOPMENT IN A MANNER CONSISTENT WITH THE
CHILD'S AGE AND COGNITIVE ABILITY;

(l) CHILDREN WITH HEARING LOSS WHO DO NOT RECEIVE EARLY
INTERVENTION AND TREATMENT FREQUENTLY REQUIRE SPECIAL
EDUCATIONAL SERVICES, WHICH, FOR THE VAST MAJORITY OF CHILDREN
IN THE STATE WITH HEARING NEEDS, ARE PUBLICLY FUNDED; AND
(m) APPROPRIATE TESTING AND IDENTIFICATION OF NEWBORN INFANTS WITH HEARING LOSS WILL FACILITATE EARLY INTERVENTION AND TREATMENT AND WILL THEREFORE SERVE THE PUBLIC PURPOSES OF PROMOTING THE HEALTHY DEVELOPMENT OF CHILDREN AND REDUCING THE NEED FOR ADDITIONAL PUBLIC EXPENDITURES.

SECTION 3. In Colorado Revised Statutes, 25-4-1003, amend (2) introductory portion and (2)(e) as follows:

25-4-1003. Powers and duties of state board and executive director - newborn screening programs - genetic counseling and education programs - rules. (2) The executive director of the department of public health and environment shall comply with the following provisions:

(e) All information gathered by the department of public health and environment, or by other agencies, entities, and individuals conducting programs and projects on newborn screening and genetic counseling and education, other than statistical information and information which that the individual PARENT OR GUARDIAN OF A NEWBORN allows to be released through his THE PARENT'S OR GUARDIAN'S informed consent, shall be is confidential. Public and private access to individual NEWBORN patient data shall be is limited to data compiled without the individual's NEWBORN's name. THE INFORMATION GATHERED PURSUANT TO THIS SUBSECTION (2)(e) DOES NOT RESTRICT THE DEPARTMENT FROM PERFORMING FOLLOW-UP SERVICES WITH NEWBORNS, THEIR PARENTS OR GUARDIANS, AND HEALTH CARE PROVIDERS.

SECTION 4. In Colorado Revised Statutes, 25-4-1004, amend (1)(b), (1)(c) introductory portion, and (2); and add (1.5) as follows:

25-4-1004. Newborn screening - advisory committee.
(1) (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 state 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 subsection (1)(c) of this section. The birthing facility where the infant is born shall forward all appropriate specimens to the laboratory operated or designated by the department. 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 laboratory shall forward the results of the testing shall be forwarded directly to the physician, primary care provider, or other primary health care provider as needed for the provision of such information to the parent, or parents, or guardians 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) subsection (1)(b) if, upon consideration of criteria set forth in paragraph (c) of this subsection (1) subsection (1)(c) of this section, the state board finds that the public health is better served by not testing infants for that condition.

(c) The state 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):

(1.5) On or before September 1, 2018, and on or before September 1 each year thereafter, the state board shall add new conditions for which infants must be tested as deemed appropriate by the department, based on the recommended uniform screening panel as recommended by the secretary of the United States department of health and human services or its successor agency.

(2) The executive director of the department of public health and environment shall assess a fee which is sufficient to cover the direct and indirect ongoing costs of such testing required by this section and to accomplish the other purposes of this part 10. Hospitals shall birthing facilities may assess a reasonable fee to be charged the parent, or parents, or guardians of the infant to cover the costs of handling the specimens, the reimbursement of laboratory costs, and the costs of providing other services, including the connection of follow-up services and care to infants identified as at risk through screening, necessary to implement the purposes of this part 10.

SECTION 5. In Colorado Revised Statutes, 25-4-1004.5, amend (2)(b), (3)(a) introductory portion, (3)(a)(V), (3)(b) introductory portion, and (3)(c); repeal (1); and add (2)(c) and (3)(b.5) as follows:

25-4-1004.5. Follow-up testing and treatment - second screening - 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) (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 first and second specimen tests with second-tier testing if necessitated by the results of the screening in order to reduce the number of false positive tests and to provide follow-up and referral services to families with a newborn whose test results under a newborn screening indicate a genetic or 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.

(c) The state board shall promulgate rules to establish and maintain appropriate follow-up services on positive screen cases in order that measures may be taken to prevent death or intellectual or other permanent disabilities. The follow-up services must include identification of newborns at risk for genetic and metabolic conditions, coordination among medical providers and families, connecting newborns who screen positive to timely intervention and appropriate referrals to specialists for follow-up and diagnostic testing, and additional duties as determined by the department.

(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:
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.

(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:

(b.5) The laboratory operated by the laboratory services division in the department, or the laboratory designated by the department, as applicable, must remain open a minimum of six days per week every week of the year.

(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 money in the newborn screening and genetic counseling cash funds is exempt from section 24-75-402.

SECTION 6. In Colorado Revised Statutes, 25-4-1004.7, amend (2)(a)(I) introductory portion, (2)(a)(I)(A), (2)(a)(I)(C), (2)(a)(II), (3)(a), and (5); repeal (1), (2)(a)(I)(B), (3)(b), and (4)(a); and add (7), (8), (9), and (10) as follows:
25-4-1004.7. Newborn hearing screening - 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

(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 REVIEWING INFORMATION AND STATISTICS GATHERED
DURING THE NEWBORN HEARING SCREENING PROGRAM AND providing
recommendations to hospitals BIRTHING FACILITIES, 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 BEST
PRACTICES for hearing screening of newborn infants, which
methodologies shall PRACTICES MUST be objective and physiologically
based and which shall MUST not include a requirement that the initial
newborn hearing screening be performed by an audiologist; AND

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

(C) Guidelines AND BEST PRACTICES 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
MUST consist of at least seven NINE members. who shall be appointed by
The executive director of the department of public health and
environment SHALL APPOINT MEMBERS TO THE ADVISORY COMMITTEE.
Members appointed to the committee shall MUST have training,
experience, or interest in the area of hearing conditions LOSS in children
AND SHOULD INCLUDE REPRESENTATIVES FROM RURAL AND URBAN AREAS
OF THE STATE, A PARENT WHO HAS A CHILD WITH HEARING LOSS, A
REPRESENTATIVE OF A PATIENT AND FAMILY SUPPORT ORGANIZATION, A
REPRESENTATIVE OF A HOSPITAL, A REPRESENTATIVE FROM AN
ORGANIZATION REPRESENTING CULTURALLY DEAF PERSONS, AN
AMERICAN SIGN LANGUAGE EXPERT WHO HAS EXPERIENCE IN EVALUATION
AND INTERVENTION OF INFANTS AND YOUNG CHILDREN, AND PHYSICIANS
AND AUDIOLOGISTS WITH SPECIFIC EXPERTISE IN HEARING LOSS IN
INFANTS.

(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 INFANTS BORN IN THE STATE BE SCREENED
FOR HEARING LOSS 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 BIRTHING
FACILITY shall educate the parents of infants born in such hospitals
BIRTHING FACILITIES of the importance of screening the hearing of
newborn infants and follow-up care. Education shall not be IS NOT
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.

(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".

(5) A physician, nurse, midwife, or other health professional attending a birth outside a hospital or institution shall ensure that the hearing screening is performed within thirty days of the birth and shall provide information, as established by rule of the department, to parents regarding places where the parents may have their infants' hearing screened and the importance of such the screening. The physician, nurse, midwife, or other health professional shall provide a report of any screening to the parent or guardian of the infant, the primary care provider of the infant, and the department.

(7) Upon receipt of sufficient financial resources in the newborn hearing screening cash fund, as determined by the department, to support a new information technology system for the purpose of managing the newborn hearing screening program, the department shall procure an information technology system and promulgate rules in order to implement the system.

(8) (a) The state board of health shall promulgate rules that require each of the following with information pertinent
TO THIS SECTION TO REPORT THE RESULTS OF INDIVIDUAL SCREENING TO
THE DEPARTMENT:

   (I) A BIRTHING FACILITY; OR

   (II) ANOTHER FACILITY OR PROVIDER.

(b) THE RULES MUST INCLUDE A REQUIREMENT THAT THE BIRTHING
FACILITY INCLUDE THE RESULTS OF THE HEARING SCREENING IN THE
ELECTRONIC MEDICAL RECORD OF THE NEWBORN. THE INFORMATION
SYSTEM REQUIRED IN SUBSECTION (7) OF THIS SECTION MUST ALLOW THE
RESULTS OF OUTPATIENT RESCREENINGS TO BE REPORTED TO THE
DEPARTMENT AND TO THE PARENT OR GUARDIAN OF THE NEWBORN.

(9) (a) THE STATE BOARD OF HEALTH SHALL PROMULGATE RULES
TO ESTABLISH AND MAINTAIN APPROPRIATE FOLLOW-UP SERVICES FOR
NEWBORNS AT RISK OF HEARING LOSS AS WELL AS NEWBORNS WHO FAIL TO
RECEIVE SCREENING. THE FOLLOW-UP SERVICES MUST INCLUDE
IDENTIFICATION OF NEWBORNS AT RISK FOR HEARING LOSS, COORDINATION
AMONG MEDICAL AND AUDIOLOGY PROVIDERS AND FAMILIES, CONNECTING
NEWBORNS TO TIMELY INTERVENTION, APPROPRIATE REFERRALS TO
SPECIALISTS FOR FOLLOW-UP AND DIAGNOSTIC TESTING, AND ADDITIONAL
DUTIES AS DETERMINED BY THE DEPARTMENT.

(b) THE FOLLOW-UP SERVICES MUST PROVIDE THE PARENTS WITH
INFORMATION AND RESOURCES SO THAT THE PARENTS CAN, IN A TIMELY
MANNER, LOCATE APPROPRIATE DIAGNOSTIC AND TREATMENT SERVICES
FOR THE NEWBORN.

(c) THE DEPARTMENT SHALL ALSO PROVIDE APPROPRIATE
TRAINING, ON A PERIODIC BASIS, TO BIRTHING FACILITIES AND MIDWIVES
ON THE DEPARTMENT'S SCREENING PROGRAM.

(d) THE INFORMATION GATHERED BY THE DEPARTMENT, OTHER
THAN STATISTICAL INFORMATION AND INFORMATION THAT THE PARENT OR 
GUARDIAN OF A NEWBORN ALLOWS TO BE RELEASED THROUGH THE 
PARENT'S OR GUARDIAN'S INFORMED CONSENT, IS CONFIDENTIAL. PUBLIC 
ACCESS TO NEWBORN PATIENT DATA IS LIMITED TO DATA COMPILED 
WITHOUT THE NEWBORN'S NAME. AUDIOLOGISTS AND OTHER HEALTH 
PROFESSIONALS PROVIDING DIAGNOSTIC SERVICES TO NEWBORNS AND 
THEIR FAMILIES MAY ACCESS THE INFORMATION, ON A NEWBORN-SPECIFIC 
basis, FOR THE PURPOSE OF ENTERING FOLLOW-UP INFORMATION. THE 
INFORMATION GATHERED IN ACCORDANCE WITH THIS SUBSECTION (9)(d) 
DOES NOT RESTRICT THE DEPARTMENT FROM PERFORMING FOLLOW-UP 
SERVICES WITH NEWBORNS, THEIR PARENTS OR GUARDIANS, AND HEALTH 
care providers.

(10) The executive director of the department may assess 
a fee that is sufficient to cover the ongoing direct and indirect 
costs of all initial newborn hearing screening and follow-up 
services and to accomplish the other purposes of this section, 
which fee shall be deposited into the newborn hearing screening 
cash fund created in section 25-4-1006(3). birthing facilities may 
asess a reasonable fee to be charged the parent or guardian of 
the newborn to cover the costs of providing services necessary 
to implement the purposes of this section.

SECTION 7. In Colorado Revised Statutes, 25-4-1006, amend 
(1); and add (3) and (4) as follows:

25-4-1006. Cash funds. (1) All moneys money received from 
fees collected pursuant to this part 10, except for the money received 
pursuant to section 25-4-1004.7, shall be transmitted to the state 
treasurer, who shall credit the same same to the newborn screening and
genetic counseling cash funds, which funds are hereby created. Such money shall be utilized for expenditures authorized or contemplated by and not inconsistent with the provisions of this part 10 relating to newborn screening, follow-up care, and genetic counseling and education programs and functions. All money credited to the newborn screening and genetic counseling cash funds shall be used as provided in this part 10 and shall not be deposited in or transferred to the general fund of this state or any other fund.

(3) There is hereby created the newborn hearing screening cash fund for the purpose of covering the ongoing direct and indirect costs associated with the administration of the newborn hearing screening program. All money collected pursuant to section 25-4-1004.7 shall be transmitted to the state treasurer, who shall credit it to the newborn hearing screening cash fund. The money in the cash fund at the end of any fiscal year shall remain in the cash fund and shall not be credited or transferred to the general fund or any other fund. In addition, the general assembly may appropriate money from the general fund to the department to implement the newborn hearing screening program.

(4) Money in the newborn screening and genetic counseling cash funds and the newborn hearing screening cash fund are exempt from section 24-75-402.

SECTION 8. In Colorado Revised Statutes, add 25-4-1002.5 as follows:

25-4-1002.5. Definitions. As used in this part 10, unless the context otherwise requires:
"BIRTHING FACILITY" MEANS A GENERAL HOSPITAL OR
BIRTHING CENTER LICENSED OR CERTIFIED PURSUANT TO SECTION
25-1.5-103.

(2) "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH
AND ENVIRONMENT.

(3) "STATE BOARD" MEANS THE STATE BOARD OF HEALTH IN THE
DEPARTMENT.

SECTION 9. Effective date. This act takes effect July 1, 2018.

SECTION 10. Safety clause. The general assembly hereby finds,
determines, and declares that this act is necessary for the immediate
preservation of the public peace, health, and safety.