

**DRAFT REPLACEMENT PAGES FOR MAR 37-677 - June 2014**  
**Infant Screening Tests and Eye Treatment**

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Subchapter 3

Infant Screening Tests and Eye Treatment

37.57.301 DEFINITIONS As used in this subchapter, the following definitions apply:

(1) "Health care facility" means a hospital or other facility licensed by or located in the state of Montana for the purpose of providing health care services, and which provides primary health care services for newborns at birth.

(2) "Newborn" means an infant in the first 28 days of life.

(3) "Newborn screening tests" are screening tests, procedures, or both for the following conditions:

(a) Acylcarnitine Disorders:

(i) Fatty Acid Oxidation Disorders:

(A) Carnitine uptake defect;

(B) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency;

(C) Medium-chain acyl-CoA dehydrogenase deficiency;

(D) Trifunctional protein deficiency; and

(E) Very long-chain acyl-CoA dehydrogenase deficiency;

(ii) Organic Acidemia Disorders:

(A) 3-hydroxy-3-methylglutaryl-CoA lyase deficiency;

(B) 3-Methylcrotonyl-CoA carboxylase deficiency;

(C)  $\beta$ -ketothiolase deficiency;

(D) Glutaric acidemia type I;

(E) Isovaleric acidemia;

(F) Methylmalonic acidemia (Cbl A,B);

(G) Methylmalonic acidemia (mutase deficiency);

(H) Multiple carboxylase deficiency; and

(I) Propionic acidemia;

(b) Amino Acid Disorders:

(i) Argininosuccinic acidemia;

(ii) Citrullinemia type 1;

(iii) Homocystinuria;

(iv) Maple syrup urine disease;

(v) Classic Phenylketonuria; and

(vi) Tyrosinemia type I;

(c) Biotinidase deficiency;

(d) Classical galactosemia;

(e) Congenital adrenal hyperplasia;

(f) Primary congenital hypothyroidism;

- (g) Cystic fibrosis;
- (h) Hemoglobinopathies, including:
  - (i) Hb S/β -thalassemia;
  - (ii) Hb SC disease; and
  - (iii) Hb SS disease; and
- (i) Critical congenital heart disease, including:
  - (i) hypoplastic left heart syndrome;
  - (ii) pulmonary atresia;
  - (iii) tetralogy of Fallot;
  - (iv) total anomalous pulmonary venous return;
  - (v) transposition of the great arteries;
  - (vi) tricuspid atresia; and
  - (vii) truncus arteriosus. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

Rules 37.57.302 and 37.57.303 reserved

37.57.304 NEWBORNS HOSPITALIZED FOR NEONATAL INTENSIVE CARE (1) If a newborn is hospitalized for neonatal intensive care, a specimen of its blood must be taken for testing prior to nonrespiratory treatment and no later than 48 hours of age, unless medically contraindicated, in which case the specimen must be taken as soon as the infant's medical condition permits.

(2) In the event that the initial screening blood specimen is taken at less than 24 hours of age, another screening specimen must be taken after 48 hours of age, and no later than 7 days of age.

(3) In the event that the newborn stays in a health care facility past 7 days of age, an additional screening blood specimen must be taken either at the time of discharge if the stay is less than one month, or at one month of age if the stay is one month or longer.

(4) Hospitals providing neonatal intensive care are responsible for developing and implementing a protocol to ensure a newborn hospitalized for neonatal intensive care receives screening for critical congenital heart disease. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

37.57.305 NEWBORNS OTHER THAN THOSE HOSPITALIZED FOR NEONATAL INTENSIVE CARE (1) For newborns not requiring neonatal intensive care, the required blood specimen must be taken between 24 and 48 hours of age.

(2) In the event the newborn is discharged from a health care facility prior to 24 hours of age, the blood specimen must be taken immediately before discharge and, in addition:

(a) another specimen must be taken and submitted to the department's laboratory between the second and seventh day of the newborn's life; and

- (b) the health care facility must:
  - (i) explain the reasons why it is of utmost importance to return for these tests; and
  - (ii) ensure that the parent or legal guardian of the newborn signs a statement assuming responsibility to cause a specimen to again be taken between the second and seventh day of life of the newborn and to submit it to the department for testing.
- (3) For newborns not requiring neonatal intensive care, a pulse oximetry screening for CCHD must be completed per the department's recommended protocol prior to discharge and after 24 hours of age and screening results reported to the department as required by this subchapter.
- (4) In the event the newborn is discharged from a health care facility prior to 24 hours of age, pulse oximetry screening must be completed immediately before discharge and the health care facility must:
  - (a) provide education to the newborn's family on the implications of screening prior to 24 hours of age;
  - (b) provide information on the optimal timing of a repeat screening and a location where repeat screening can be done; and
  - (c) document (a) and (b) in the newborn's medical record. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1537, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

37.57.306 TRANSFER OF NEWBORN INFANT (1) In the event of transfer of a newborn from one health care facility to another, or from a place of birth that is not a health care facility to a health care facility, a screening blood specimen must be taken and submitted by the receiving health care facility.

(2) A receiving health care facility must take specimens as necessary for follow-up tests as required by this subchapter.

(3) In the event of a transfer of a newborn from one health care facility to another, or from a place of birth that is not a health care facility to a health care facility, pulse oximetry screening for CCHD must be completed after 24 hours of age by the receiving health care facility and screening results reported to the department as required by this subchapter. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

37.57.307 INFANT BORN OUTSIDE HEALTH CARE FACILITY (1) When an infant is born outside of a health care facility and is not subsequently transferred to a health care facility for initial newborn care, it is the responsibility of one of the persons designated in 50-15-221(4)(a), (b), and (c), MCA, in the order of priority indicated therein, to cause the blood specimen to be taken and submitted, and to cause pulse oximetry screening to be performed as required by this subchapter. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398;

AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

37.57.308 NEWBORN EYE TREATMENT (1) A physician, nurse-midwife, or any other person who assists at the birth of any newborn must, within the time limit stated in (3), instill or have instilled into each conjunctival sac of the newborn, erythromycin (0.5%) ophthalmic ointment or drops from single-use tubes or ampules.

(2) A prophylactic agent referred to in (1) above may not be flushed from a newborn's eyes after instillation.

(3) The prophylactic agent must be administered to a newborn within one hour after its birth unless it is physically impossible to obtain the agent within that time, in which case the agent must be administered as soon as possible. (History: 50-1-202, MCA; IMP, 50-1-202, MCA; NEW, 1987 MAR p. 2147, Eff. 11/28/87; TRANS, from DHES, 2001 MAR p. 398; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

Rules 37.57.309 through 37.57.314 reserved

37.57.315 TRANSFUSION: WHEN BLOOD SPECIMEN TAKEN (1) If a newborn needs a transfusion, blood specimens for the tests required by this subchapter must be taken before the transfusion takes place unless medically contraindicated.

(2) If the newborn is transfused prior to collection of the initial newborn screening specimen, a screening specimen must be taken 90 to 120 days after the last transfusion to screen for classical galactosemia and hemoglobinopathies. This specimen is in addition to those required elsewhere in this chapter. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; NEW, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

37.57.316 REPORTING SCREENING RESULTS (1) If screening results on an infant's blood specimen are within the expected or normal range the department will report the results to the submitter of the specimen and, in addition, to the infant's healthcare provider(s) upon request.

(2) If the infant's blood specimen is of unsatisfactory quality for testing, the department will notify the submitter of the need for collection of an additional specimen. The submitter must ensure collection of this specimen in a timely manner within three days of notification.

(3) If screening results on an infant's blood specimen are outside the expected or normal range:

(a) the department will report results to the submitter of the specimen and to the healthcare provider(s) for the infant. Recommendations for follow-up actions contained in the report are determined by the department;

(b) the provider(s) will ensure that all repeat screening, confirmatory testing, or both, as recommended, is collected and submitted to the department or an approved laboratory within 48 hours or as clinically appropriate;

(c) if a referral to a contracted specialist is made by the department, the specialist will ensure that all confirmatory testing results and final diagnosis are reported to the department within one week of the determination of the final diagnosis.

(4) An approved laboratory for confirmatory testing following out-of-range blood screening results includes any state or territorial health department laboratory and any laboratory within their jurisdictions which is approved by them, a U.S. public health service laboratory, a laboratory operated by the U.S. Armed Forces or Veteran's Administration, a Canadian provincial public health laboratory, and any laboratory licensed under the provisions of the Clinical Laboratories Improvement Act of 1967, as amended.

(5) Each person in charge of any health care facility and each person responsible under ARM 37.57.307 for a birth occurring outside a health care facility must report to the department regarding pulse oximetry screening per department guidelines. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

Rules 37.57.317 through 37.57.319 reserved

37.57.320 RESPONSIBILITIES OF REGISTRAR OF BIRTH:

ADMINISTRATOR OF HEALTH CARE FACILITY (1) Each person in charge of any health care facility and each person responsible under ARM 37.57.307 for a birth occurring outside a health care facility must:

(a) ensure that a blood specimen is taken from each newborn for which the health care facility or person is responsible, in conformity with this subchapter, for the purpose of performing newborn screening tests;

(b) be certain that the specimen to be forwarded to the laboratory is adequate for testing purposes;

(c) within 24 hours after the taking of the specimen, cause such specimen to be forwarded to the department's laboratory by either courier or first-class mail or its equivalent;

(d) record in the newborn's medical record the date of taking of the test specimen and the results of the tests performed when reported by the department;

(e) ensure that pulse oximetry is performed per the department's recommended protocol for the purpose of performing newborn screening for CCHD as follows:

(i) ensure that the screening is performed on equipment that has been approved by the FDA for use on newborns and is motion tolerant;

(ii) ensure that screening is performed by licensed staff who have been trained on the screening procedure and protocol;

(iii) record in the newborn's medical record the date, time, and screening results;

(iv) ensure that the pulse oximetry screening results are reported to DPHHS as required by this subchapter;

(v) ensure that a policy and procedure is in place for immediate follow-up of a failed CCHD screen; and

(f) use educational materials provided by the department and must provide education to the newborn's family on the following:

(i) the conditions that may be detected through bloodspot screening and pulse oximetry screening;

(ii) the importance of newborn screening tests to detect potentially life-threatening conditions;

(iii) the process for collecting bloodspot screening and conducting pulse oximetry screening; and

(iv) after hearing all the benefits of newborn screening and the risks involved in refusing testing, a parent/legal guardian may refuse either of the above screenings. In that case, the parent/legal guardian must sign a waiver for the newborn's medical record in which they accept responsibility for adverse consequences. A copy of this waiver must be provided to the department. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)

37.57.321 STATE LABORATORY (1) Only those newborn screening blood tests performed by the department laboratory or a laboratory approved by the department, meet the requirements of 50-19-201, 50-19-202, 50-19-203, and 50-19-204, MCA.

(2) Dried blood specimens remaining after newborn screening test completion are the property of the department laboratory and will be stored for one calendar year prior to destruction. Any dried blood specimens sent to a laboratory approved by the department for testing will be destroyed after one year by the approved laboratory. An exception is made for screening specimens with results that are out of range which may be kept for quality improvement and new method development within the laboratory. These specimens may be stored by the laboratory for an indefinite period of time. (History: 50-19-202, MCA; IMP, 50-19-203, MCA; Eff. 12/31/72; AMD, Eff. 5/6/74; AMD, 1985 MAR p. 1612, Eff. 11/1/85; TRANS, from DHES, 2001 MAR p. 398; AMD, 2003 MAR p. 1298, Eff. 7/1/03; AMD, 2008 MAR p. 44, Eff. 1/18/08; AMD, 2014 MAR p. 1411, Eff. 7/1/14.)