Rules of
Department of Health
and Senior Services
Division 25—Division of Administration
Chapter 36—Testing for Metabolic Diseases

Title

19 CSR 25-36.010 Testing for Metabolic and Genetic Disorders ......................................................3
PURPOSE: State law requires that all infants be tested for phenylketonuria and other metabolic diseases as prescribed by the Department of Health. This rule establishes the metabolic and genetic disorders that each infant shall be tested for and, the collection and submission procedures to be used by health care providers in sending specimens to the State Public Health Laboratory. This rule also establishes the fee for newborn screening.

(1) As used in this rule—
   (A) Newborn screening means the testing of infants for the following metabolic and genetic disorders: phenylketonuria (PKU), primary hypothyroidism, galactosemia, and abnormal hemoglobins; and
   (B) Submitter(s) means a person or persons responsible for collecting specimens under section 191.331, RSMo, for newborn screening tests.

(2) Submitters shall collect specimens on the collection forms provided in specimen collection kits purchased from the Department of Health. The submitter of the specimen shall provide all information requested in the specimen collected kit.

(3) Specimens shall be prepared in accordance with standard medical practices. The timing of specimen collection shall be determined by the conditions specified in subsections (3)(A) through (C) below. All specimens shall be submitted within forty-eight (48) hours of collection to the State Public Health Laboratory in Jefferson City.

   (A) A specimen shall be taken from all infants before being discharged from the hospital or birthing facility regardless of feeding status. A specimen collected within the first seventy-two (72) hours of life and after twenty-four (24) hours of protein feeding is considered adequate for newborn screening. A second, or repeat, specimen shall be required if the initial specimen was collected before twenty-four (24) hours of protein feeding. The repeat specimen shall be collected within the first seven (7) days of life and after twenty-four (24) hours of protein feeding.

   (B) Specimens from ill or premature infants shall be collected after their conditions have stabilized even if protein feeding has not been initiated, preferably within the first seven (7) days of life. If no protein feeding took place before the infant’s condition stabilized, a second specimen shall be collected after twenty-four (24) hours of protein feeding.

   (C) If an infant has been transferred from one hospital to another, the records shall clearly indicate if a specimen for newborn screening was collected and submitted. If no specimen was collected, the hospital the infant is transferred to shall collect a specimen and submit it within five (5) days of the transfer.

(4) Parents who object to testing on religious grounds shall state those objections in writing. The written objection shall be filed with the attending physician, certified nurse midwife, public health facility, ambulatory surgical center or hospital. Upon receipt, the attending physician, certified nurse midwife, public health facility, ambulatory surgical center or hospital shall send a copy of the written objection to the Department of Health.

(5) The health care provider caring for an infant with a presumptive post-test report from newborn screening shall report a definitive diagnosis within thirty (30) days of the date of diagnosis for that infant to the Department of Health, Bureau of Disabilities Prevention, P.O. Box 570, Jefferson City, MO 65102-0570.

(6) A fee of up to twenty-five dollars ($25) shall be charged for each specimen collection kit. Each specimen collection kit represents one (1) specimen. If repeat specimens are required under this rule, the fee shall be charged for each specimen collection kit required to obtain each specimen. The Department of Health and Senior Services may collect the fee from any entity or individual described in 191.331.1, RSMo.
