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

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 25—Division of Administration

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19 CSR 25-36.010 Testing for Metabolic and Genetic Disorders

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 hypothyrodism, 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, PO Box 570, Jefferson City, MO 65102-0570.

(6) Effective July 1, 2005, a fee of up to fifty dollars ($50) shall be charged for each specimen collection kit used to obtain the initial blood specimen. If the State Public Health Laboratory recommends repeat specimens, additional specimen collection kits will be made available without the fee being imposed. Repeat specimens requests, other than those recommended by the State Public Health Laboratory, will be subject to the fee and the fee shall be charged for each specimen collection kit required to obtain each repeat specimen. The Department of Health and Senior Services may collect the fee from any entity or individual described in 191.331.1, RSMo.

AUTHORITY: sections 701.322, RSMo Supp. 2004 and 191.331 and 192.006, RSMo 2000. This rule was previously filed as 13 CSR 50-143.010 and 19 CSR 20-36.010. Original rule filed Sept. 29, 1965, effective Oct. 13, 1965. Amended: Filed April 6, 1967, effective April 16, 1967. Rescinded and readopted: Filed Sept. 30, 1980, effective April 11, 1981. Rescinded: Filed Aug. 1, 1986, effective Oct. 27, 1986. Readopted: Filed Aug. 4, 1986, effective Oct. 27, 1986. Amended: Filed March 16, 1987, effective May 28, 1987. Amended: Filed Jan. 15, 1993, effective Sept. 9, 1993. Changed to 19 CSR 25-36.010 Jan. 1, 1995. Emergency amendment filed Aug. 4, 1997, effective Aug. 28, 1997, expired Feb. 26, 1998. Amended: Filed Aug. 4, 1997, effective Jan. 30, 1998. Amended: Filed April 9, 2002, effective Oct. 30, 2002. Amended: Filed Feb. 1, 2005, effective July 30, 2005.*

**Original authority: 191.331, RSMo 1965, amended 1985, 1992, 1993, 1995, 1997; 192.006, RSMo 1993, amended 1995; and 701.322, RSMo 1993, amended 2001.*