

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 25—Missouri State Public Health Laboratory
Chapter 36—Testing for Metabolic Diseases

PROPOSED AMENDMENT

19 CSR 25-36.010 Testing for Metabolic and Genetic Disorders. The Department is amending sections (6), (7), and (8).

PURPOSE: This amendment makes grammatical changes, clarifies wording for consistency, and increases the fee ceiling for the specimen screening.

(6) The health care provider caring for an infant with an abnormal high-risk test *[report]* **result** from newborn screening shall report a definitive diagnosis within thirty (30) days of the date of the diagnosis for that infant to the appropriate newborn screening contracted follow-up center as contracted by the Department of Health and Senior Services. The department shall prescribe and furnish all necessary reporting forms for this purpose.

(7) The *[medical professional]* **health care provider** responsible for the medical care of the infant shall provide newborn screening education to the parents or guardians. Educational materials regarding the newborn screening conducted by the state, including the disorders screened for and the management and treatment of these disorders are made available by the Department of Health and Senior Services. The educational materials may be ordered at www.health.mo.gov/warehouse/eliterature.html or by contacting the Department of Health and Senior Services' Newborn Screening Program at 800-877-6246.

(8) Effective *[August]* **July 1, [2015] 2019**, a fee of up to *[ninety-five]* **one hundred thirty-five** dollars *[(95)]* **(\$135)** shall be charged for each specimen collection form used to obtain a newborn screening blood specimen. If the **Missouri** State Public Health Laboratory determines a submitted blood specimen to be unsatisfactory for testing due to laboratory or transportation issues, then a replacement specimen collection form will be made available without the fee being imposed. The Department of Health and Senior Services may collect the fee from any entity or individual described in section 191.331.1, RSMo.

AUTHORITY: section 192.006, RSMo 2000, [and] section[s] 191.331, RSMo Supp. 2013, and section 191.332, RSMo [Supp. 2013] 2017. 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 Rescinded and readopted: Filed Sept. 30, 1980, effective April 11, 1981.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. Amended: Filed June 12, 2007, effective Jan. 30, 2008. Amended: Filed Jan. 29, 2015, effective July 30, 2015.

Original authority: 191.331, RSMo 1965, amended 1985, 1992, 1993, 1995, 1997; 191.332, RSMo 2001, amended 2005; and 192.006, RSMo 1993, amended 1995.

PUBLIC COST: This proposed amendment will cost state agencies twenty seven thousand nine hundred dollars (\$27,900) annually with projected first year fee increase; twenty five thousand five hundred seventy five dollars (\$25,575) in the aggregate with projected second year fee increase; and up to three hundred thirty two thousand four hundred seventy five dollars (\$332,475) in the aggregate annually thereafter with implementation of additional fee increases up to the established fee cap.

PRIVATE COST: This proposed amendment will cost private entities five hundred eighty four thousand six hundred forty dollars (\$584,640) annually with projected first year fee increase; two hundred twenty one thousand seven hundred sixty dollars (\$221,760) in the aggregate annually with the projected second year fee increase; and up to three million two hundred twenty five thousand six hundred dollars (\$3,225,600) in the aggregate annually thereafter with implementation of additional fee increases up to the established fee cap.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, State Public Health Laboratory, Bill Whitmar, Laboratory Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*