

APPENDIX B - REGULATIONS

Kansas Administrative Regulation 28-4-501

NOTE: Online K.A.R.s are updated annually. To obtain the latest version of a regulation please check the Kansas Register to see if an updated version has been published, or contact the agency enacting the regulation.

28-4-501 Definitions.

(a) "Applicable income" means the total monies received by all adult members of the family based on any of the following, with the addition of nontaxable benefits from any private, state, and federal funding sources:

(1) The total amount of adjusted gross income reported on one of the federal income tax forms 1040, 1040A, or 1040EZ, including a copy of all W-2 forms filed by each adult member of the family;

(2) the six most recent pay stubs; or

(3) a letter of anticipated earnings from the employer of each adult member of the family if the most recent federal income tax form does not reflect current income.

(b) "Birth attendant" means the person assisting with an out-of-institution delivery of the infant, in the absence of a physician.

(c) "Borderline hypothyroid" means an abnormally low level of thyroxine and a higher than normal level of thyroid-stimulating hormone in the blood, the combination of which is not usually indicative of hypothyroidism.

(d) "Cash assets" means accessible money, including savings accounts, certificates of deposit, checking accounts, stocks, and bonds. This term shall not include individual retirement accounts and retirement plans.

(e) "Department" means the Kansas department of health and environment.

(f) "Eligible person" means an individual who qualifies for any necessary treatment products or medically necessary food treatment products, or both.

(g) "Family," for the purposes of these regulations, means an eligible person who meets one of the following conditions and all other persons who reside in the home with the eligible person;

(1) Resides with and is considered to be a dependent of the person's parents, stepparents, or legal guardian for income tax purposes; or

(2) establishes a separate residence and is no longer considered a dependent of the person's parents, stepparents, or legal guardian for income tax purposes.

The term "family" shall not include any person who leases or rents a portion of the residence or who lives with the other persons who are not responsible for the financial support of the eligible person.

(h) "Galactosemia" means the disease of genetic origin due to galactose uridyl transferase enzyme deficiency in which the individual is completely or partially incapable of normal metabolism of galactose, which results in an abnormal increase in the concentration of galactose in the blood.

(i) "Hemoglobin disease" means the presence of abnormal hemoglobin and the absence of adult hemoglobin, the combination of which is indicative of disease and requires ongoing medical treatment.

(j) "Hemoglobin trait" means the presence of abnormal hemoglobin, which is not indicative of disease and does not usually require ongoing medical treatment.

(k) "Hypothyroidism" means a congenital disease in which the individual is unable to produce

thyroxine normally, which may be detected by an abnormally low serum level of thyroxine and an abnormally high serum level of thyroid-stimulating hormone in the blood. For purposes of these newborn screening regulations, this term shall exclude diseases referred to as secondary hypothyroidism.

(l) "Institution" means a hospital or other organized agency providing obstetrical services.

(m) "Kit" means the multiple-page laboratory requisition with the attached filter paper to be used for blood collection and with a place for identifying the infant, physician, and sending agency data. The kits shall be provided by the department.

(n) "Laboratory" means the division of health and environmental laboratories, Kansas department of health and environment.

(o) "Maple syrup urine disease" and "MSUD" mean an inherited disease of amino acid metabolism that causes acidosis, central nervous system symptoms, and urine that can smell sweet like maple syrup.

(p) "Medical specialist" means a medical doctor who has training in the treatment of a specific disease entity and who has a contract with the department to serve as a consultant and to provide or direct diagnosis and treatment services.

(q) "Medically necessary food treatment product" means a specifically formulated product that has less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of any inherited metabolic disease. This term shall not include any foods that are naturally low in protein.

(r) "Necessary treatment product" means a medical protein source used under the direction of a physician to treat specific metabolic diseases in order to prevent, delay, or reduce medical complications.

(s) "Newborn screening coordinator" means the designee in the department providing the follow-up program activities.

(t) "Other genetic disease" means any condition inherited in a recognized pattern that can be detected in a filter paper blood specimen and that the secretary has designated as part of the newborn screening battery of tests.

(u) "Phenylketonuria" and "PKU" mean any disease, usually due to a single enzyme deficiency of genetic origin, in which the individual is completely or partially incapable of normal metabolism of phenylalanine, which results in an abnormal increase in the concentration of phenylalanine in the blood.

(v) "Presumptive positive" means a screening test result that indicates the possible presence of a disease, requiring further testing to confirm or not confirm the diagnosis.

(w) "Secretary" means the secretary of the Kansas department of health and environment.

(x) "Sending agency" means the agency or person identified on the kit to be the recipient of the report.

(y) "Specimen" means the saturated blood spots on the filter paper and the laboratory requisition with complete identifying data on the infant, physician, and sending agency. (Authorized by K.S.A. 65-101 and 65-180, as amended by 2006 SB 579, Sec. 1; implementing K.S.A. 65-180, as amended by 2006 SB 579, Sec. 1, and 65-181; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; amended April 14, 2000; amended, T-28-7- 5-06, July 5, 2006; amended Oct. 20, 2006.)

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28-4-502 Responsibility to obtain specimen.

(a) The administrative officer or other person in charge of each institution or the attending physician are responsible for obtaining an adequate initial specimen for newborn screening on infants born in that institution.

(b) The attending physician or other birth attendant is responsible for obtaining an adequate specimen for newborn screening on infants born outside of an institution.

(c) The attending physician or other birth attendant is responsible for obtaining repeat specimens when needed to complete the screening process. (Authorized by K.S.A. 65-101; implementing K.S.A. 65-181; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987.)

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28-4-503 Timing of specimen collection.

(a) Initial specimens from healthy full-term infants born in an institution shall be obtained before discharge or from three through five days of age if the infant is still hospitalized.

(b) Initial specimens from sick or premature infants born in an institution shall be obtained from seven through 10 days of age if the infant is still hospitalized or before discharge, if earlier than seven days.

(c) If the infant is transferred from the institution of birth to another institution before 24 hours of age, the receiving institution shall obtain the specimen.

(d) Specimens shall be obtained before blood transfusions, regardless of the age of the infant.

(e) Initial specimens from infants born outside of an institution shall be obtained from three through five days of age.

(f) Repeat screening of or diagnostic test specimens from infants shall be obtained before 21 days of age.

(g) If an infant is less than 24 hours old when the initial specimen is taken, a repeat specimen shall be obtained and submitted for testing to the laboratory. (Authorized by K.S.A. 65-101; implementing K.S.A. 1999 Supp. 65-181; effective, T- 87-48, Dec. 19, 1986; effective May 1, 1987; amended April 14, 2000.)

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28-4-504 Methods of specimen collection.

(a) The specimen shall be collected using kits provided by the department.

(b) The form provided with the kit shall be completed before collection of the blood specimen.

(c) The outlined circles on the filter paper portion of the kit shall be saturated with blood in the manner specified on the filter paper.

(d) The specimen shall be delivered by carrier or mailed first-class to the laboratory after the blood has dried and not later than 24 hours from time of collection. (Authorized by K.S.A. 65-101; implementing K.S.A. 1998 Supp. 65-181; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; amended April 14, 2000.)

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28-4-505 Unsatisfactory specimens.

(a) Unsatisfactory specimens shall be retained by the department. The sending agency or facility shall be notified that the specimen is unsatisfactory. The physician shall be notified that the specimen is unsatisfactory with a request to submit another specimen.

(b) Specimens shall be labeled unsatisfactory when one of the following criteria is met:

(1) Identifying information is missing.

(2) More than 10 days have elapsed since the date of collection.

(3) The specimen is of unacceptable quality for analysis. (Authorized by K.S.A. 65-101; implementing K.S.A. 1998 Supp. 65-181; effective, T- 87-48, Dec. 19, 1986; effective May 1, 1987; amended April 14, 2000.)

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28-4-506 (Authorized by K.S.A. 65-101; implementing K.S.A. 65-180; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; revoked May 10, 1996.)

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28-4-507 (Authorized by K.S.A. 65-101; implementing K.S.A. 65-181; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; revoked May 10, 1996.)

Kansas Administrative Regulation 28-4-508

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28-4-508 (Authorized by K.S.A. 65-101; implementing K.S.A. 65-181; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; revoked May 10, 1996.)

Kansas Administrative Regulation 28-4-509

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28-4-509 Registry.

(a) The registry shall be a computerized data system that includes the diagnosed individuals' name, birth-date, unique identification number, diagnosis, address including telephone number, parental names and addresses, guardian, nuclear family size and health status.

(b) Persons or guardians of minor children with a confirmed diagnosis of phenylketonuria, hypothyroidism or galactosemia shall forward to the newborn screening coordinator any address and health status changes within three months of the change. (Authorized by K.S.A. 65-101; implementing K.S.A. 65-180; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987.)

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28-4-510 Diagnosis and monitoring.

(a) Each person with a confirmed diagnosis of any of the diseases specified in K.S.A. 65-180, and amendments thereto shall be eligible to receive medical specialist monitoring upon the department's annual receipt of the person's current address, insurance data, and documentation of continued medical need from a medical specialist.

(b) Each medical specialist shall meet the following requirements:

(1) Provide consultation and diagnosis; and

(2) provide and coordinate ongoing monitoring. (Authorized by K.S.A. 65-101; implementing K.S.A. 65-180, as amended by 2006 SB 579, Sec. 1; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; amended, T-28-7-5-06, July 5, 2006; amended Oct. 20, 2006.)

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28-4-511 Test refusal. Refusal to take part in the testing procedure shall be documented in the child's record at the institution or physician's office or both. (Authorized by K.S.A. 65- 101; implementing K.S.A. 65-182; effective, T-87- 48, Dec. 19, 1986; effective May 1, 1987.)

Kansas Administrative Regulation 28-4-512

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28-4-512 Parental education.

(a) Providers of prenatal health care shall discuss and distribute written material describing the newborn screening program as a component of the prenatal care to pregnant women.

(b) Prior to obtaining the specimen for newborn screening, the person responsible for obtaining the specimen shall inform the parent or parents about the newborn screening program, including how the test can be refused. (Authorized by K.S.A. 65-101; implementing K.S.A. 65- 182; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987.)

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28-4-513 Professional education.

(a) Consultation with medical specialists shall be available without charge to primary care providers and others involved in the care of persons at risk for or diagnosed with phenylketonuria, congenital hypothyroidism, galactosemia, or hemoglobin diseases and traits.

(b) Notification letters and telephone calls reporting abnormal test results to the physicians shall contain information including interpretation of data and recommendations for follow-up.

(c) Upon request, workshops and other educational presentations concerning newborn screening shall be provided by the department when a specific need is identified.

(d) The newborn screening coordinator and personnel in the newborn screening section of the laboratory shall respond to telephone and written inquiries concerning specimens within five working days of receipt. (Authorized by K.S.A. 65-101; implementing K.S.A. 1998 Supp. 65-180; effective, T-87-48, Dec. 19, 1986; effective May 1, 1987; amended April 14, 2000.)