Chapter DHS 115

SCREENING OF NEWBORNS FOR CONGENITAL AND METABOLIC DISORDERS

Note: Chapter HSS 115 was created as an emergency rule effective November 1, 1992. Chapter HSS 115 was renumbered ch. HFS 115 under s. 13.93 (2m) (b) 1., Stats., and corrections were made under s. 13.93 (2m) (b) 6. and 7., Stats, Register, May, 1998, No. 509. Chapter HFS 115 was renumbered chapter DHS 115 under s. 13.92 (4) (b) 1., Stats., and corrections made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637.

DHS 115.01 Authority and purpose. This chapter is promulgated under the authority of ss. 253.13 (1) and 227.11 (2), Stats., to specify the congenital and metabolic disorders for which newborn infants are to be screened by means of a sample of blood taken from an infant shortly after birth and tests performed on that sample by the state laboratory of hygiene.

History: Cr. Register, May, 1993, No. 449, eff. 6−1−93; correction made under s. 13.93 (2m) (b) 7., Stats., Register, July, 1995, No. 475.

DHS 115.02 Applicability. This chapter applies to the attending physician licensed under ch. 448, Stats., nurse−midwife certified under s. 441.15, Stats., or other attendant at the birth of an infant born in Wisconsin, to the infant and the infant's parents or guardian, and to the state laboratory which carries out tests on the sample of blood taken from the infant.

History: Cr. Register, May, 1993, No. 449, eff. 6−1−93.

DHS 115.03 Definitions. In this chapter:

(1) "Congenital disorder" means a disorder present at birth, either inherited or due to an influence occurring during gestation up to birth.

(2) "Department" means the Wisconsin department of health services.

(3) "ICD−9−CM" means the *International Classification of Diseases, 9th Revision, Clinical Modification, October 1, 1991.*

(4) "Medical consultant" means a physician licensed to practice medicine or osteopathy under ch. 448, Stats., who has expertise in treatment of one or more of the conditions listed under s. DHS 115.04.

(5) "Metabolic disorder" means a disorder of the chemical processes that take place in the body.

(6) "Screening" means checking each member of a population to identify presumptive medical conditions that indicate that diagnostic testing for congenital or metabolic disorders is needed.

(7) "State laboratory" means the state laboratory of hygiene under s. 36.25 (11), Stats.

History: Cr. Register, May, 1993, No. 449, eff. 6−1−93; correction in (2) made under s. 13.92 (4) (b) 6., Stats., Register January 2009 No. 637.

DHS 115.04 Congenital and metabolic disorders. Blood samples taken from newborns as required under s. 253.13 (1), Stats., shall be tested by the state laboratory for all of the following conditions:

(1) Phenylketonuria (PKU), ICD−9−CM 270.1.

(2) Galactosemia, ICD−9−CM 271.1.

(3) Congenital hypothyroidism, ICD−9−CM 243.

(4) Sickle cell disease and related hemoglobin abnormalities, ICD−9−CM 282.6.

(5) Biotinidase deficiency, ICD−9−CM 266.9.

(6) Congenital adrenal hyperplasia, ICD−9−CM 255.2.

(7) Cystic fibrosis, ICD−9−CM 277.0.

(8) Medium chain acyl−coenzyme A dehydrogenase deficiency (MCAD) and related disorders of lipid metabolism, ICD−9−CM 272.9.

(9) Maple Syrup Urine Disease, ICD−9−CM 270.3.

(10) Homocystinuria, ICD−9−CM 270.4.

(11) Tyrosinemia, ICD−9−CM 270.2.

(12) Citrullinemia, ICD−9−CM 270.6.

(13) Argininosuccinic Acidemia, ICD−9−CM 270.6.

(14) Severe Combined Immunodeficiency and related conditions of immunodeficiency, ICD−9−CM 279.2.

History: Cr. Register, May, 1993, No. 449, eff. 6−1−93; emerg. am. (5) and (6), cr. (7), eff. 1−31−95; correction in (intro.) made under s. 13.93 (2m) (b) 7., Stats., Register, July, 1995, No. 475; am. (5) and (6), cr. (7), Register, July, 1995, No. 475, eff. 8−1−95; am. (intro.) and (1) to (6), cr. (8), Register, December, 1999, No. 528, eff. 1−1−00; emerg. cr. (9) to (13), eff. 10−12−02; CR 02−136: cr. (9) to (13) Register March 2003 No. 567, eff. 4−1−03; emerg. cr. (14), eff. 1−1−08; CR 08−005: cr. (14) Register June 2008 No. 630, eff. 7−1−08.

DHS 115.05 Laboratory tests. (1) PROCEDURES. The state laboratory shall establish procedures, with the approval of the department, for obtaining blood specimens for the testing required under s. 253.13 (1), Stats., and this chapter, performing tests and reporting results of tests performed to the infant's physician and the department as required under s. 253.13 (4), Stats.

(2) ADDITIONAL TESTS FOR RESEARCH AND EVALUATION PURPOSES. The department may direct the state laboratory to perform other tests on specimens for research and evaluation purposes related to congenital and metabolic disorders or laboratory procedures. In directing that additional testing be performed, the department shall ensure that all applicable laws relating to protection of human subjects of research are observed.

(3) FEES. The newborn screening sample collection card fee shall be $109 for each newborn screened to cover the costs under sub. (1) and to fund follow−up services and other activities under s. 253.13 (2), Stats.

History: Cr. Register, May, 1993, No. 449, eff. 6−1−93; corrections in (1) made under s. 13.93 (2m) (b) 7., Stats., Register, July, 1995, No. 475; **CR 12−025: cr. (3) Register May 2013 No. 689, eff. 6−1−13.**

DHS 115.06 Criteria for adding or deleting conditions. In determining which disorders are to be added or deleted from s. DHS 115.04, the department shall seek the advice and guidance of medical consultants, staff of the state laboratory and other persons who have expertise and experience in dealing with congenital and metabolic disorders. Criteria to be considered in adding or deleting disorders shall include all of the following:

(1) Characteristics of the specific disorder, including disease incidence, morbidity and mortality.

(2) The availability of effective therapy and potential for successful treatment.

(3) Characteristics of the test, including sensitivity, specificity, feasibility for mass screening and cost.

(4) The availability of mechanisms for determining the effectiveness of test procedures.

(5) Characteristics of the screening program, including the ability to collect and analyze specimens reliably and promptly, the ability to report test results quickly and accurately and the existence of adequate follow−up and management programs.

(6) The expected benefits to children and society in relation to the risks and costs associated with testing for the specific condition.

History: Cr. Register, May, 1993, No. 449, eff. 6−1−93; am. (intro.) and (1) to (5), Register, December, 1999, No. 528, eff. 1−1−00.