Chapter DHS 115

SCREENING OF NEWBORNS FOR CONGENITAL 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 and 227.11 (2), Stats., to specify the congenital disorders for which each newborn is screened and tested.

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; CR 14–074: am. Register July 2015 No. 715, eff. 8–1–15; EmR1920: emerg. am., eff. 10–15–19; CR 19–064: am Register December 2019 No. 768, eff. 1–1–20.

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.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; CR 14–074: am. Register July 2015 No. 715, eff. 8–1–15.

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–10–CM" means the *International Classification of Diseases*, *10th Revision, Clinical Modification*.

(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; CR 14–074: am. (3) Register July 2015 No. 715, eff. 10–1–15.

DHS 115.04 Congenital disorders. Pursuant to s. 253.13 (1), Stats., blood samples taken from each newborn shall be tested for all of the following conditions:

(1) (a) Phenylketonuria (PKU), ICD–10–CM–E70.0.

(b) Hyperphenylalaninemia, ICD–10–CM–E70.1.

(2) Galactosemia, ICD–10–CM–E74.21.

(3) Congenital hypothyroidism, ICD–10–CM–E03.1.

(4) Hemoglobinopathies, including all of the following:

(a) Sickle cell disease, ICD–10–CM–D57.1.

(b) Hemoglobin S–beta Thalassemia, ICD–10–CM–D57.40.

(c) Hemoglobin SC disease, ICD–10–CM–D57.20.

(d) Hemoglobin disease other, ICD–10–CM–D58.2.

(5) Biotinidase deficiency, ICD–10–CM–D81.810.

(6) Congenital adrenal hyperplasia, ICD–10–CM–E25.0.

(7) Cystic fibrosis, ICD–10–CM–E84.9.

(8) Fatty acid oxidation disorders, including all of the following:

(a) Medium–chain acyl–CoA dehydrogenase deficiency, ICD–10–CM–E71.311.

(b) Long–chain L–3–Hydroxy acyl–CoA dehydrogenase deficiency, ICD–10–CM–E71.318.

(c) Very long–chain acyl–CoA dehydrogenase deficiency, ICD–10–CM–E71.310.

(cm) Carnitine palmitoyltransferase IA deficiency, ICD–10–CM–E71.318.

(d) Carnitine palmitoyltransferase II deficiency, ICD–10–CM–E71.318.

(e) Carnitine–acylcarnitine translocase deficiency, ICD–10–CM–E71.318.

(f) Glutaric acidemia type II, ICD–10–CM–E71.313.

(g) 2, 4–Dienoyl–CoA reductase deficiency, ICD–10–CM–E71.318.

(h) Carnitine uptake defect, ICD–10–CM–E71.41.

(i) Medium/short–chain hydroxy CoA dehydrogenase deficiency, ICD–10–CM–E71.318.

(j) Medium–chain ketoacyl–CoA thiolase deficiency, ICD–10–CM–E71.318.

(9) Maple Syrup Urine Disease, ICD–10–CM–E71.0.

(10) Homocystinuria, ICD–10–CM–E72.11.

(11) Tyrosinemia types I, II, and III, ICD–10–CM–E70.21.

(12) Citrullinemia types I and II, ICD–10–CM–E72.23.

(13) Argininosuccinic acidura, ICD–10–CM–E72.22.

(14) Severe Combined Immunodeficiency and related conditions of immunodeficiency, ICD–10–CM–D81.9.

(15) Organic acidemias, including all of the following:

(a) Glutaric acidemia type I, ICD–10–CM–E72.3.

(b) Propionic acidemia, ICD–10–CM–E71.121.

(c) Methylmalonic acidemia (CBL A, B, C, D; MUT), ICD–10–CM–E71.120.

(d) Isovaleric acidemia, ICD–10–CM–E71.110.

(e) 3–Methylcrotony1–CoA carboxylase deficiency, ICD–10–CM–E71.19.

(f) Multiple carboxylase deficiency, ICD–10–CM–D81.818.

(g) 3–Methylglutaconic aciduria, ICD–10–CM–E71.111.

(h) beta–Ketothiolase deficiency, ICD–10–CM–E71.19.

(i) 2–Methyl–3–hydroxbutyric aciduria, ICD–10–CM–E71.19.

(j) 3–Hydroxy–3–methylglutaric aciduria, ICD–10–CM–E71.118.

(15m) Spinal muscular atrophy, ICD–10–CM–G12.9.

(16) Critical congenital heart disease, including all of the following:

(a) 1. Coarctation of the aorta, ICD–10–CM–Q25.1.

2. Atresia of aorta, ICD–10–CM–Q25.2.

3. Stenosis of aorta, ICD–10–CM–Q25.3.

(b) 1. Double outlet right ventricle, ICD–10–CM–Q20.1.

2. Double outlet left ventricle, ICD–10–CM–Q20.2.

(c) Ebstein's anomaly, ICD–10–CM–Q22.5.

(d) 1. Hypoplastic left heart syndrome ICD–10–CM–Q23.4.

2. Congenital mitral stenosis or atresia, ICD–10–CM–Q23.2.

(e) 1. Interrupted aortic arch, ICD–10–CM–Q25.4.

2. Atresia of aorta, ICD–10–CM–Q25.2.

3. Stenosis of aorta, ICD–10–CM–Q25.3.

(f) 1. Pulmonary valve atresia, ICD–10–CM–Q22.0.

2. Other congenital malformations of the pulmonary valve, ICD–10–CM–Q22.3.

3. Atresia of pulmonary artery, ICD–10–CM–Q25.5.

(g) Single ventricle heart disease variants other than HLHS, including all of the following:

1. Hypoplastic right heart syndrome, ICD–10–CM–Q22.6.

2. Other congenital malformations of the tricuspid valve ICD–10–CM–Q22.8.

3. Congenital malformations of the tricuspid valve unspecified, ICD–10–CM–Q22.9.

4. Double inlet ventricle, ICD–10–CM–Q20.4.

(h) Tetralogy of fallot, ICD–10–CM–Q21.3.

(i) 1. Total anomalous pulmonary venous return, ICD–10–CM–Q26.2.

2. Anomalous pulmonary venous connection, unspecified, ICD–10–CM–Q26.4.

3. Partial anomalous pulmonary venous connection, ICD–10–CM–Q26.3.

(j) Transposition of the great vessels, ICD–10–CM–Q20.3.

(k) Tricuspid atresia and stenosis, ICD–10–CM–Q22.4.

(L) Truncus arteriosus, ICD–10–CM–Q20.0.

(17) Pompe Disease, ICD–10–CM–E74.02.

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; CR 14–074: am. (intro.), cr. (15), (16) Register July 2015 No. 715, eff. 8–1–15, and renum. (1) to (1) (a) and am., cr. (1) (b), am. (2), (3), r. and recr. (4), am. (5) to (7), r. and recr. (8), am. (9) to (14), r. and recr. (15), am. (16) Register July 2015 No. 715, eff. 10–1–15; correction in (15) (g) made under s. 35.17, Stats., Register September 2015 No. 717; EmR1920: emerg. am. (title), (intro.), cr. (8) (cm), (15m), eff. 10–15–19; CR 19–064: am. (title), (intro.), cr. (8) (cm), (15m) Register December 2019 No. 768, eff. 1–1–20; **EmR2131: emerg. cr. (17), eff. 1–10–22; CR 21–051: cr. (17) Register May 2022 No. 797, eff. 6–1–22.**

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.

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; CR 14–074: (3) renum. to 115.055 and am. Register July 2015 No. 715, eff. 8–1–15.

DHS 115.055 Fees. The newborn screening sample collection card fee for testing a newborn under s. 253.13 (1), Stats., and this chapter shall be $109 to cover the costs of testing and to fund follow–up services and other activities under s. 253.13 (2), Stats.

History: CR 14–074: renum. from 115.05 (3) and am. Register July 2015 No. 715, eff. 8–1–15.

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.