PROPOSED ORDER OF
DEPARTMENT OF HEALTH SERVICES
TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services proposes an order to renumber and amend DHS 115.05 (3); to amend 115.01, 115.02, and 115.04 (intro.) and (1) to 14, and (15) and (16) as created by this order; and to create 115.04 (15) and (16), relating to screening newborns for congenital and metabolic disorders.

RULE SUMMARY

Statute interpreted
Section 253.13, (1) Stats.

Statutory authority
Section 227.11 (2) (a) and 253.13 (1), Stats.

Explanation of agency authority

Section 227.11 (2) (a) reads: Rule-making authority is expressly conferred on an agency as follows:
(a) Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:

1. A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

2. A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

Section 253.13 (1): (1) TESTS; REQUIREMENTS. The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15, or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these tests.

Related statute or rule

See the "Statute interpreted" section.

Plain language analysis
As provided in s. 253.13 (1), Stats. (2011-12), ch. DHS 115 specifies the congenital and metabolic orders for which newborns must be screened by means of a blood sample shortly after birth and tested by the Wisconsin State Laboratory of Hygiene (WSLH). 2013 Wisconsin Act 135 modified s. 253.13 (1) Stats., relating to infant blood tests to provide that the required screening may be performed by methods in addition to blood testing. Under the proposed rules the department revises ch. DHS 115 to conform the rules to s. 253.13 (1), Stats.

The proposed rules add critical congenital heart disease (CCHD) and organic acidemias (OA) as conditions for which newborns must be tested. CCHD is usually described as those congenital cardiac malformations in which surgical or catheter-based therapy is necessary within the first months of life, and is screened for by use of pulse oximetry. In September 2010, the U.S. Department of Health and Human Services, Discretionary Advisory Committee on Heritable Disorders in Newborns and Children added CCHD to its *Recommended Uniform Screening Panel Core Conditions*. To date, 35 states have added CCHD screening to their newborn screening panel.

OA is a group of inherited disorders that lead to an abnormal buildup of particular acids known as organic acids in the body for which the WSLH currently tests newborns. Though the criteria under s. DHS 115.06 was met for OA to be added to the list of congenital and metabolic disorders for which WSLH must test blood samples, the disorders were inadvertently omitted from subsequent revisions of s. DHS 115.04.

The department promulgated emergency rules effective July 3, 2014, to add CCHD and OA to the list of conditions for which newborns must be screened.

Currently, the conditions listed in s. DHS 115.04, are coded using the *International Classification of Diseases, 9th Revision* (ICD-9 CM). The U.S. Department of Health and Human Services requires health care providers, health plans, and health care clearinghouses to transition to the *International Classification of Diseases, 10th Revision* (ICD-10 CM) effective October 1, 2015. To ensure consistency among health care providers and to facilitate the transition in this order, the proposed rule lists the ICD-10 CM codes for the CCHD and OA conditions proposed, and the conditions already listed in s. DHS 115.04.

Summary of, and comparison with, existing or proposed federal regulations
There appears to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rules.

Comparison with rules in adjacent states
Illinois, Iowa, Michigan, and Minnesota state law require that newborns be screened for congenital and metabolic disorders, including CCHD and organic acidemias.

Illinois:
Illinois does not list in administrative rules, the congenital or metabolic disorders for which infants are screened.

Iowa:

Iowa does not list in administrative rules, the congenital or inherited disorders for which infants are screened.

Michigan:
Michigan does not list in administrative rules, the congenital or metabolic disorders for which infants are screened.

Minnesota:
Minnesota does not list in administrative rules, the congenital or metabolic disorders for which infants are screened.

Summary of factual data and analytical methodologies
The DHS Secretary's Advisory Committee on Newborn Screening (Committee) recommended to the department, and the department concurred with the recommendation to add CCHD to the list of congenital and metabolic disorders for which newborns must be screened.

The WSLH tests newborns for OA, a group of inherited disorders that lead to an abnormal buildup of particular acids, known as organic acids, in the body. Though OA was determined to have met the criteria under s. DHS 115.06 for being added to the list of congenital and metabolic disorders for which WSLH must test the blood samples of newborns, the conditions were inadvertently omitted from the list of conditions in s. DHS 115.04 during subsequent revisions of the rule section.

Analysis and supporting documents used to determine effect on small business
The department proposes to revise ch. DHS 115 to conform the rules to s. 253.13 (1), Stats., as revised under 2013 Wisconsin Act 135 so that the required newborn screening may be performed by methods in addition to blood testing. The department also proposes to add CCHD and OA to the list of congenital and metabolic disorders for which newborns must be tested. Section 253.13 (1), Stats., requires attending physicians, nurse-midwives, and certified midwives to cause every infant born in Wisconsin to be screened for the congenital and metabolic disorders specified by the department by rule. To comply with s. 253.13 (1), Stats., hospitals, stand-alone birth centers, physicians, nurse-midwives, certified midwives, and other entities (purchasers) purchase newborn screening sample collection cards for $109 from the WSLH for use when obtaining the newborn's blood sample for testing. The addition of CCHD and OA to the list of congenital and metabolic disorders under s. DHS 115.04 for which newborns must be tested does not increase the current fee or impose any additional fees to purchasers of newborn screening sample collection cards.

Costs to providers for screening for CCHD are indeterminate. Pulse oximetry is the recognized screening method for CCHD. The cost of a reliable hand held device, with a reusable probe, costs about $500, with probe wraps costing about $.60 each. Administering the pulse oximetry testing on newborns averages about three minutes per baby and is usually conducted by nurses. Some of the costs to providers for screening for CCHD have been mitigated through the Wisconsin SHINE Project (Screening Hearts in Newborns), a pilot project of the University of Wisconsin School of Medicine and Public Health, the Medical College of Wisconsin, the department, and the WSLH, which works to create a safety net for all babies born in Wisconsin by educating healthcare providers, improving access to screening and diagnostic technology, and creating a statewide CCHD screening and data collection system. The Wisconsin SHINE project has supplied pulse oximeters to hospitals and midwives who did not have them.

The inclusion of OA in the list of disorders for which newborns must be tested will not impose any additional costs to providers because the WSLH currently tests newborns for OA including propionic acidemia, methylmalonic acidemia, and related organic acidemias.

Effect on small business

Based on the foregoing analysis, the proposed rules are anticipated to have little or no economic impact on businesses.

Agency contact person

Susan Uttech, Department of Health Services, Bureau Director, Community Health Promotion, susan.uttech@wi.gov 608-267-3561

Statement on quality of agency data

The department relied on the following information for the rules and analysis:

1. The Centers for Disease Control (CDC)

2. The United States Department of Health and Human Services Discretionary Advisory Committee on Heritable Disorders in Newborns and Children

3. The Wisconsin Newborn Screening Program – Condition Nomination Form

4. The Wisconsin SHINE Project

5. Ng, B. and Hokanson, J. (2010), Missed Congenital Heart Disease in Neonates. Congenital Heart Disease, 5: 292–296. doi: 10.1111/j.1747-0803.2010.00418.x

6. Beissel, D. J., Goetz, E. M. and Hokanson, J. S. (2012), Pulse Oximetry Screening in Wisconsin. Congenital Heart Disease, 7: 460–465. doi: 10.1111/j.1747-0803.2012.00651.x

7. Conditions View. Newborn Screening Coding and Terminology Guide. U.S. National Library of Medicine. Data Standards for Electronic Reporting. Available at: http://newbornscreeningcodes.nlm.nih.gov/nb/sc/query?reportDefault=reportConditionDetails&conditions=conditions&applications=applications&submit=go. Accessed November 26, 2014.

8. Newborn Blood Screening Panel of Diseases. Available at: http://www.slh.wisc.edu/clinical/newborn/health-care-professionals-guide/nbs-test-panel-of-diseases/#asa. Accessed December 1, 2014.

Place where comments are to be submitted and deadline for submission

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin Administrative Rules Website at http://adminrules.wisconsin.gov after the hearing is scheduled.

RULE TEXT

SECTION 1. DHS 115.01 and 115.02 are amended to read:

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~~and tested.

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~~.

SECTION 2. DHS 115.04 (intro.) is amended to read:

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

SECTION 3. DHS 115.04 (1) is renumbered DHS 115.04 (1) (a) and amended to read:

DHS 115.04 (1) (a) Phenylketonuria (PKU), ~~ICD-9-CM 270.1~~ICD-10-CM-E70.0.

SECTION 4. DHS 115.04 (1) (b) is created to read:

DHS 115.04 (1) (b) Hyperphenylalaninemia, ICD-10-CM-E70.1

SECTION 5. DHS 115.04 (2) and (3) are amended to read:

DHS 115.04 **(2)** Galactosemia, ~~ICD-9-CM 271.1~~ ICD-10-CM-E74.21.

(3) Congenital hypothyroidism, ~~ICD-9-CM 243~~ICD-10-CM- E03.1.

SECTION 6. DHS 115.04 (4) is repealed and recreated to read:

DHS 115.04 (4) Hemoglobinopathies, including all of the following:

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

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

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

(d) Hemoglobin disease other, IDC-10-CMD58.2.

SECTION 7. DHS 115.04 (5) to (7) are amended to read:

DHS 115.04 (5) Biotinidase deficiency, ~~ICD-9-CM 266.9~~ICD-10-CM-D81.810.

(6) Congenital adrenal hyperplasia, ~~ICD-9-CM 255.2~~ ICD-10-CM-E25.0.

(7) Cystic fibrosis, ~~ICD-9-CM 277.0~~ ICD-10-CM-E84.

SECTION 8. DHS 115.04 (8) is repealed and recreated to read:

DHS 115.04 (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.

(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.

SECTION 9. DHS 115.04 (9) to (14) are amended to read:

DHS 115.04 **(9)** Maple Syrup Urine Disease, ~~ICD-9-CM 270.3~~ICD-10-CM-E71.0.

(10) Homocystinuria, ~~ICD-9-CM 270.4~~ICD-10-CM-E72.11.

(11) Tyrosinemia (types I, II, and III),~~ICD-9-CM 270.2~~ ICD-10-CM-E70.21.

(12) Citrullinemia (types I and II),~~ICD-9-CM 270.6~~ ICD-10-CM-E72.23.

(13) Argininosuccinic ~~Acidemia, ICD-9-CM 270.6~~ acidura, ICD-10-CM-E72.22.

(14) Severe Combined Immunodeficiency and related conditions of immunodeficiency, ~~ICD-9-CM 279.2~~ICD-10-CM-D81.9.

SECTION 10. DHS 115.04 (15) and (16) are created to read:

DHS 115.04 **(**15) Propionic acidemia, methylmalonic acidemia, and related organic acidemias, ICD-9-CM 270.3 and ICD-9-CM 270.7.

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

(a) 1. Coarctation of the aorta, ICD-9-CM 747.10.

2. Atresia of aorta, ICD-9-CM 747.22.

3. Stenosis of aorta, ICD-9-CM 747.22.

(b) 1. Double outlet right ventricle, ICD-9-CM 745.11.

2. Double outlet left ventricle, ICD-9-CM 745.19.

(c) Ebstein's anomaly, ICD-9-CM 746.2.

(d) 1. Hypoplastic left heart syndrome (HLHS), ICD-9-CM 746.7.

2. Congenital mitral stenosis or atresia, ICD-9-CM 746.5.

(e) 1. Interrupted aortic arch, ICD-9-CM 747.11.

2. Atresia of aorta, ICD-9-CM 747.22.

3. Stenosis of aorta, ICD-9-CM 747.22.

(f) 1. Pulmonary valve atresia, ICD-9-CM 746.01.

2. Other congenital malformations of the pulmonary valve, ICD-9-CM 746.

3. Atresia of pulmonary artery, ICD-9-CM 747.31.

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

1. Hypoplastic right heart syndrome, ICD-9-CM 746.89.

2. Other congenital malformations of the tricuspid valve ICD-9-CM 746.8.

3. Congenital malformations of the tricuspid valve unspecified, ICD-9-CM 746.9.

4. Common ventricle, ICD-9-CM 745.3.

(h) Tetralogy of fallot, ICD-9-CM 745.2.

(i) 1. Total anomalous pulmonary venous return, ICD-9-CM 747.41.

2. Anomalous pulmonary venous connection, unspecified, ICD-9-CM 474.49.

3. Partial anomalous pulmonary venous connection, ICD-9-CM 747.42.

(j) Transposition of the great vessels-complete, ICD-9-CM 745.10.

(k) Tricuspid atresia and stenosis, ICD-9-CM 746.1.

(L) Truncus arteriosus, ICD-9-CM 745.0.

SECTION 11. DHS 115.04 (15), as created by this rule, is repealed and recreated to read:

DHS 115.04 **(**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-Methylgulutaconic 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.

SECTION 12. DHS 115.04 (16), as created by this rule, is amended to read:

DHS 115.04 (16) (a) 1. Coarctation of the aorta, ~~ICD-9-CM 747.10~~ ICD-10-CM Q 25.1.

2. Atresia of aorta, ~~ICD-9-CM 747.22~~ ICD-10-CM Q25.2.

3. Stenosis of aorta, ~~ICD-9-CM 747.22~~ICD-10-CM Q 25.3.

(b) 1. Double outlet right ventricle, ~~ICD-9-CM 745.11;~~ICD-10-CM Q20.1.

2. Double outlet left ventricle, ~~ICD-9-CM 745.19~~ICD-10-CM Q20.2.

(c) Ebstein's anomaly, ~~ICD-9-CM 746.2~~ICD-10-CM Q22.5.

(d) 1. Hypoplastic left heart syndrome (HLHS), ~~ICD-9-CM 746.7~~ICD-10-CM Q23.4.

2. Congenital mitral stenosis or atresia, ~~ICD-9-CM 746.5~~ICD-10-CM Q23.2.

(e) 1. Interrupted aortic arch, ~~ICD-9-CM 747.11~~ ICD-10-CM Q25.4.

2. Atresia of aorta, ~~ICD-9-CM 747.22~~ICD-10-CM Q25.2.

3. Stenosis of aorta, ~~ICD-9-CM 747.22~~ICD-10-CM Q25.3.

(f) 1. Pulmonary valve atresia, ~~ICD-9-CM 746.01~~ICD-10-CM Q22.0.

2. Other congenital malformations of the pulmonary valve, ~~ICD-9-CM 746~~ICD-10-CM Q22.3.

3. Atresia of pulmonary artery, ~~ICD-9-CM 747.31~~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-9-CM 746.89~~ICD-10-CM Q 22.6.

2. Other congenital malformations of the tricuspid valve ~~ICD-9-CM 746.89~~ ICD-10-CM Q22.8.

3. Congenital malformations of the tricuspid valve unspecified, ~~ICD-9-CM 746.9~~ICD-10-CM Q22.9.

4. ~~Common ventricle, ICD-9-CM 745.3~~Double inlet ventricle, ICD-10-CM Q20.4.

(h) Tetralogy of fallot, ~~ICD-9-CM 745.2~~ICD-10-CM Q21.3.

(i) 1. Total anomalous pulmonary venous return, ~~ICD-9-CM 747.41~~ICD-10-CM Q26.2.

2. Anomalous pulmonary venous connection, unspecified, ~~ICD-9-CM 474.49~~ICD-10-CM Q26.4.

3. Partial anomalous pulmonary venous connection, ~~ICD-9-CM 747.42~~ ICD-10-CM Q26.3.

(j) Transposition of the great ~~vessels-complete, ICD-9-CM 745.~~vessels, ICD-10-CM Q20.3.

(k) Tricuspid atresia and stenosis, ~~ICD-9-CM 746.1~~ICD-10-CM Q22.4.

(L) Truncus arteriosus, ~~ICD-9-CM 745.0~~ICD-10-CM Q20.0.

SECTION 13. DHS 115.05 (3) is renumbered DHS 115.055 and amended to read:

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 ~~for each newborn screened~~ to cover the costs ~~under sub. (1)~~ of testing and to fund follow-up services and other activities under s. 253.13 (2), Stats.

SECTION 14. EFFECTIVE DATES. (1) Except as provided in sub. (2), the rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register as provided in s. 227.22 (2) (intro.), Stats.

(2) The treatment of s. DHS 115.04 (1) (a) and (b) and (2) to (14), the repeal and recreation of s. DHS 115.04 (15), and the amendment of s. DHS 115.05 (16) take effect on October 1, 2015.