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EmR1410
ORDER OF THE
DEPARTMENT OF HEALTH SERVICES
TO ADOPT EMERGENCY RULES

The Wisconsin Department of Health Services hereby adopts emergency rules to renumber and amend DHS 115.05 (3); to amend 115.01, 115.02, and 115.04 (intro.); and to create 115.04 (15) and (16) relating to screening newborns for congenital and metabolic disorders.

The statement of scope for this rule, SS 057-14, was approved by the Governor on June 5, 2014, published in Register 702, on June 14, 2014, and approved by Secretary Rhoades on June 25, 2014.

This emergency rule was approved by the Governor on June 27, 2014.

FINDING OF EMERGENCY

The Department of Health Services finds that an emergency exists and that the adoption of an emergency rule is necessary for the immediate preservation of the public health, safety and welfare. The facts constituting the emergency are as follows:

1. Section 253.13 (1), Stats., requires attending physicians and nurses licensed under s. 441.15, Stats., to cause every infant born in each hospital or maternity home, prior to the infant's discharge 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, Stats., or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these tests.

2. Section DHS 115.04 lists the disorders for which newborns must be tested under s. 253.13 (1), Stats.

3. Critical congenital heart disease (CCHD) is described as those congenital cardiac malformations in which surgical or catheter-based therapy is necessary within the first months of life. There are 12 lesions commonly considered as CCHD. In some circumstances, infants with CCHD may be asymptomatic and have a normal physical examination prior to routine hospital discharge or completion of home birth care. Unrecognized CCHD can result in death or disability shortly after hospital discharge.

4. Death due to unrecognized CCHD from 2002 to 2006 occurred in 1:38,397 Wisconsin births and death or re-hospitalization occurred in 1:24,684 Wisconsin births before two weeks of age. The median age at death due to unrecognized CCHD was 4.5 days.

5. Pulse oximetry, a point of care testing, is the recognized screening method for CCHD.

6. Prior to 2013 Wisconsin Act 135, adding pulse oximetry screening for CCHD to the mandatory panel was not permitted because testing for congenital and metabolic disorders under s. 235.13 (1), Stats. (2011-12) was explicitly limited to blood testing. Section 253.13 (1), Stats., as amended by 2013 Wisconsin Act 135, now allows testing for congenital and metabolic disorders using other screening methods including blood testing.

7. The Wisconsin State Laboratory of Hygiene (WSLH) tests newborns for organic acidemias (OA), a group of inherited disorders that lead to an abnormal buildup of particular acids, known as organic acids, in the body.

8. Abnormal levels of organic acids in the blood (organic acidemia), urine (organic aciduria), and tissues can be toxic and can cause serious health problems. A baby affected with an OA is usually well at birth and for the first few days of life. The usual clinical presentation is that of toxic encephalopathy and includes vomiting, poor feeding, neurologic symptoms such as seizures and abnormal tone, and lethargy progressing to coma. Outcome is improved by diagnosis and treatment in the first ten days of life.

9. Propionic acidemia and methylmalonic acidemia are two types of organic acidemias. In propionic academia and methylmalonic acidemia, the body is unable to process certain parts of proteins and lipids (fats) properly. In most cases, the features of propionic acidemia become apparent within a few days after birth. Propionic acidemia affects about 1 in 100,000 people in the United States. The effects of methylmalonic acidemia, which usually appear in early infancy, vary from mild to life-threatening. Without treatment, this disorder can lead to coma and death in some cases. This condition occurs in an estimated 1 in 50,000 to 100,000 people.

10. 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.

11. The process for promulgating permanent rules may take 24 months to complete, or longer if the department is unable to submit the permanent rules to the legislature prior to its last general business floor period in 2016.

RULE SUMMARY

Statute interpreted
Section 253.13 (1), Stats.

Statutory authority
Sections 227.11 (2) (a) and 253.13 (1) and (4) (b) 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) and (4) (b) reads: (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.

(4) (b) The department may require reporting in connection with the tests performed under this section for use in statistical data compilation and for evaluation of infant screening programs.

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 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 this emergency order the department revises ch. DHS 115 to conform the rules to s. 253.13, Stats.

The emergency order adds CCHD and 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 federal 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 intends to promulgate corresponding permanent rules to replace these emergency rules, except that the department intends to also propose, as permitted under s. 253.13 (4), Stats., reporting requirements in the proposed permanent rules.

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 emergency rules.

Comparison with rules in adjacent states
For the past ten years Illinois, Iowa, Michigan and Minnesota have mandated that newborns be screened for organic acidemias to include propionic acidemia and methylmalonic acidemia as part of their state's newborn screening program. Also, each of these four states require by law that newborns be screened for CCHD using pulse oximetry screening and provide reports on all pulse oximetry results if sufficient funds are available to do so. Only Iowa has an administrative rule for CCHD.

Illinois:
Illinois 410 ILCS 240/1.10 (b) "The Department shall require that screening tests for critical congenital heart disease be performed at birthing hospitals and birth centers in accordance with a testing protocol adopted by the Department, by rule, in line with current standards of care, such as pulse oximetry screening…" 77 Ill. Adm. Code 661.10 Responsibility for Screening explains that a Genetic and Metabolic Diseases Advisory Committee will recommend to the Department when an additional disorder should be added to the screening panel. Implementation of the Department's determination is subject to that determination's adoption by rule. This process is similar to Wisconsin's procedure for adding a disorder.

Iowa:
Iowa Code s. 136A.5A requires that each Iowa newborn "shall receive a critical congenital heart disease screening by pulse oximetry or other means as determined by rule, in conjunction with the metabolic screening required pursuant to section 136A.5A." Section 136.5A was added as part of 2013 Act, Ch. 140 Section 91 and Section 92 to address critical congenital heart disease screening; however the administrative rule is not yet written. Administrative Code 641 IAC 4.3 (1) states that CCHD will be included in the state's newborn screening panel as included in the recommended uniform screening panel as approved by the United States Secretary of Health and Human Services."

Michigan:

Under Michigan statute, MCLS, s. 333.5431 (1) (i) refers to CCHD generally as "other treatable but otherwise disabling conditions as designated by the department." The Michigan Department of Community Health website lists all (55) of the disorders included in their screening panel which includes CCHD.

Minnesota:
Minn. Stats. s. 144.1251 (1) (a) requires testing and reporting as follows "each licensed hospital or state licensed birthing center or facility that provides maternity and newborn care services shall provide screening for congenital heart disease to all newborns prior to discharge using pulse oximetry screening." The Minnesota Department of Health's procedure for implementation includes: communicating CCHD screening protocol requirements; providing information to hospitals; providing training; establishing the mechanism for required data collection; coordinating implementation of universal standardized screening; and acting as a resources for providers which is similar to Wisconsin's approach.

Summary of factual data and analytical methodologies
The 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 or metabolic disorders for which newborns must be screened.

The WSLH tests newborns 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.

Analysis and supporting documents used to determine effect on small business
The department under this emergency order revises ch. DHS 115 to conform the rules to s. 253.13, Stats., as revised under 2013 Wisconsin Act 135 so that the required newborn screening may be performed by methods in addition to blood testing. Also under this emergency order, the department adds 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 is 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 it is usually conducted by nurses. Some of the costs to providers for screening for CCHD have been mitigated through the Wisconsin SHINE Project (**S**creening **H**earts **i**n **Ne**wborns), a pilot project through 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 emergency 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:

http://cdc.gov

US Secretary of Health and Human Services, Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

Wisconsin Newborn Screening Program – Condition Nomination Form

http://wisconsinshine.org

Ng B, Hokanson J. Missed congenital heart disease in neonates. Congenit Heart Dis. 2010;5:292-6.

Bissel DlJl Goetz EM, Hokanson J.S> Pulse Oximetry for Congenital Heart Disease in Wisconsin. Congenit Heart Dis. 2011;6:521-2

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 each newborn ~~infants are to be~~is 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:

https://docs.legis.wisconsin.gov/document/administrativecode/DHS 115.04**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 (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 270.7.

(16) The following Critical Congenital Heart Disease (CCHD) including all of the following:

(a) Aortic arch atresia or hypoplasia, ICD-9-CM 747.21 and 747.22.

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

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

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

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

(f) Neonatal Ebstein’s anomaly, ICD-9-CM 746.2.

(g) Pulmonary atresia, ICD-9-CM 746.01.

(h) Single ventricle heart disease variants (other than HLHS) Tetralogy of fallot, ICD-9-CM 745.2.

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

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

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

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

SECTION 3. 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 253.13 (1) 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 4. EFFECTIVE DATE. The rules contained in this order shall take effect as emergency rules upon publication in the official state newspaper, as provided in s. 227.24 (1) (c), Stats.

Wisconsin Department of Health Services

Dated: June 27, 2014

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Kevin Moore, Deputy Department Secretary

SEAL: