WISCONSIN DEPARTMENT OF HEALTH SERVICES
PROPOSED ORDER TO ADOPT PERMANENT AND EMERGENCY RULES

Clearinghouse Rule 19-064

The Wisconsin Department of Health Services (Department) proposes an order to amend ch. DHS 115 (title), s. DHS 115.01, 115.04 (title) and (intro.), create ss. DHS 115.04 (8) (cm) and DHS 115.04 (15m), relating to screening of newborns for congenital and metabolic disorders.

FINDING OF EMERGENCY

The Department contracts with the Wisconsin State Laboratory of Hygiene to test most newborns for certain congenital disorders that are listed by the Department in s. DHS 115.04. The department proposes to add Carnitine Palmitoyltransferase IA ("CPT IA") and Spinal Muscular Atrophy ("SMA") to the rule.

Preservation of the public health and welfare requires screening newborns for CPT IA and SMA. These disorders present serious health risks in childhood and are unlikely to be detected and prevented in the absence of newborn screening. Interventions are reasonably available at this time, and have been shown, in well-designed studies, to be safe and effective in preventing or ameliorating serious health consequences stemming from a delayed or missed diagnosis of these disorders.

RULE SUMMARY

Statute interpreted
Section 253.13 (1), Stats.

Statutory authority
Sections 253.13 (1) and (4) (b) and 227.11 (2) (a), Stats.

Explanation of agency authority
Under s. 253.13(1), Stats., the Department has the authority to specify the congenital disorders for which newborn infants are screened and tested.

Related statute or rule
Section 253.13 (1), Stats.

Plain language analysis
As provided in s. 253.13 (1), Stats., ch. DHS 115 specifies the congenital disorders for which newborns must be screened by means of a blood sample shortly after birth and tested by the Wisconsin State Lab of Hygiene. 2013 Wisconsin Act 135 modified s. 253.13 (1) Stats., relating to infant blood tests so 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 rule language to s. 253.13, Stats. The emergency order adds Carnitine Palmitoyltransferase IA (CPT IA) deficiency and Spinal Muscular Atrophy (SMA) as conditions for which newborns must be tested.

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

Illinois:

Illinois 410 ILCS 240/1.10 (b) 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.

Illinois does screen for CPT1A, but is not currently screening for SMA. However, legislation was passed to screen for SMA, but a testing method is still under development.

Iowa:

Iowa Code s. 136A.5A 641—4.3(136A) Iowa newborn screening program (INSP). This program provides comprehensive newborn screening services for hereditary and congenital disorders for the state. 4.3(1) Newborn screening policy. All newborns and infants born in the state of Iowa shall be screened for all congenital and inherited disorders specified by the center and approved by the state board of health.

Iowa does not currently screen for CPT IA or SMA, however, their Congenital and Inherited Disorders Advisory Committee may vote on whether to recommend the addition of SMA to the panel in January, 2019 depending on the availability and outcome of the needs assessment for adding SMA.

Michigan:

Under Michigan statute, MCLS, s. 333.5431 (1) (i) refers to CPT IA 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 CPT IA. [Michigan's legislatively-mandated committee voted to add SMA to Michigan's NBS panel and are currently working through their approval process]. MCL 333.5430 established a legislatively-mandated advisory committee that is charged with meeting annually. This committee has the authority to add disorders to the NBS panel and approve fee increases associated with adding a disorder.

Michigan has been screening for CPT IA since 2005 but does not currently screen for SMA. However, their legislatively-mandated committee voted to add SMA to Michigan's NBS panel and are working through their approval process.

Minnesota:

Minn. Stats. s. 144.125 TESTS OF INFANTS FOR HERITABLE AND CONGENITAL DISORDERS. Subdivision 1. Duty to perform testing. (a) It is the duty of (1) the administrative officer or other person in charge of each institution caring for infants 28 days or less of age, (2) the person required in pursuance of the provisions of section 144.215, to register the birth of a child, or (3) the nurse midwife or midwife in attendance at the birth, to arrange to have administered to every infant or child in its care tests for heritable and congenital disorders according to subdivision 2 and rules prescribed by the state commissioner of health. Subd. 2. Determination of tests to be administered.

Minnesota currently screens for both CPT IA since 2003 and SMA since 2018.

Summary of factual data and analytical methodologies

The Department's Advisory Committee on Newborn Screening (Committee) recommended to the Department, and the Department concurred with the recommendation to add CPT IA and SMA to the

list of congenital disorders for which newborns must be screened. Carntine palmitoyltransferase IA (CPT IA) deficiency is a fatty acid oxidation disorder associated with hypoketotic hypoglycemia and liver failure. Children with CPTIA present with hypoglycemia, liver dysfunction and encephalopathy, cholestatic jaundice and hepatomegaly, as well as renal dysfunction manifesting as renal tubular acidosis, when viral illness or prolonged fasting occurs. Prior to the episodes of metabolic crisis, they typically have normal growth and development. Studies have also found evidence for an association between infant mortality associated with infectious disease and homozygosity for CPT IA mutations. SMA is a neurodegenerative autosomal recessive genetic disease with an estimated incidence of 1 in 10,000 births. It affects the motor neurons in the spinal cord, and involves multiple organs. Cause of death is usually respiratory failure. There are five types of SMA, based on severity. SMA type 0 and I has the earliest onset, and is most severe. Type II usually presents by 18 months of age; children with type II can usually sit but cannot stand or walk. Type III manifests between 18 months and 10 years; children can learn to stand and walk, but usually lose these skills over time. Finally, Type IV is the mildest form, and may not show symptoms until adulthood. It was determined that CPT IA and SMA met the criteria under s. DHS 115.06 for being added to the list of congenital disorders for which WSLH must test the blood samples of newborns.

Analysis and supporting documents used to determine effect on small business

TBD, pending an economic impact analysis.

Effect on small business

The proposed rules are expected to have no effect on small business, pending an economic impact analysis.

Agency contact person

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Statement on quality of agency data

The Department relied on the following information for the rules and analysis: The Centers for Disease Control and Prevention, US Secretary of Health and Human Services, Department's Advisory Committee on Heritable Disorders in Newborns and Children, and Wisconsin Newborn Screening Program – Condition Nomination Form (the form is found here: https://www.dhs.wisconsin.gov/newbornscreening/process-additions.htm).

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 notice of public hearing and deadline for submitting comments will be published in the Wisconsin Administrative Register and to the department's website, at https://www.dhs.wisconsin.gov/rules/permanent.htm. Comments may also be submitted through the Wisconsin Administrative Rules Website, at: https://docs.legis.wisconsin.gov/code/chr/active.

RULE TEXT

SECTION 1. Chapter DHS 115 (title) is amended to read:

(title) SCREENING OF NEWBORNS FOR CONGENITAL ~~AND METABOLIC~~ DISORDERS.

SECTION 2. DHS 115.01 is 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 and tested.

SECTION 3. DHS 115.04 (title) and (intro.) are amended to read:

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

SECTION 4. DHS 115.04 (8) (cm) is created to read:

DHS 115.04 **(8) (cm)** Carnitine palmitoyltransferase IA deficiency, ICD-10-CM-E71.318.

SECTION 5. DHS 115.04 (15m) is created to read:

DHS 115.04 **(15m)** Spinal muscular atrophy, ICD-10-CM-G12.9.

SECTION 6. EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in § 227.22 (2) (intro), Stats.