Clearinghouse Rule 21-051

DEPARTMENT OF HEALTH SERVICES **STATE OF WISCONSIN**
Office of Legal Counsel
F-02318 (12/2018)

WISCONSIN DEPARTMENT OF HEALTH SERVICES
PROPOSED ORDER TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services ("the Department") proposes an order to create ss. DHS 115.04 (17), relating to screening of newborns for congenital disorders.

RULE SUMMARY

Statute interpreted
Section 253.13, Stats.

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

Explanation of agency authority
Under s. 253.13, 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, 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 ("WSLH"). This test is referred to as the "newborn screening panel."

In order to fulfill its statutory duty to identify those disorders by rule, s. DHS 115.06 requires that the Department 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" to determine whether to add or delete disorders to the newborn screening panel. Panels of experts—comprised of medical practitioners, experts on genetics, pediatrics, and medical ethics—met and recommended adding Pompe disease to the newborn screening panel, and the Department's Secretary approved the recommendation to add Pompe disease to the newborn screening panel. Accordingly, this order adds Pompe disease as a congenital disorder 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 rule.

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 Illinois Department of Public Health 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.

In 2015, Illinois added Pompe disease to the screening panel of conditions.

Iowa:

Iowa Code s. 136A.5A 641—4.3(136A) Iowa newborn screening program. 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 Pompe disease.

Michigan:

Under Michigan statute, MCLS, s. 333.5431 (1), the Michigan Department of Community Health website lists all (56) of the disorders included in their screening panel. 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 newborn screening panel and approve fee increases associated with adding a disorder.

In 2017, Michigan added Pompe disease to the screening panel of conditions.

Minnesota:

Minn. Stat. s. 144.125, Tests of Infants for Heritable and Congenital Disorders. Minnesota statute requires that the administrative officer or other person in charge of each institution caring for infants 28 days or less of age arrange to have administered to every infant or child in its care tests for heritable and congenital disorders. The statute further provides that the Minnesota Commissioner of Health periodically revise the list of tests to be administered under Minn. Stat. s. 144.125 based on "advances in medical science, new and improved testing methods, or other factors that will improve the public health . . . [,] adequacy of analytical methods to detect the heritable or congenital disorder, the ability to treat or prevent medical conditions caused by the heritable or congenital disorder, and the severity of the medical conditions caused by the heritable or congenital disorder." Minn. Stat. s. 144.125, subd. 2. The list of tests to be performed may also be revised if the changes are recommended by the advisory committee established under Minn. Stat. s. 144.1255, approved by the commissioner, and published in the State Register. Revisions are exempt from the rulemaking requirements in chapter 14 of the Minnesota Statutes.

In 2017, Minnesota added Pompe disease to the screening panel of conditions.

Summary of factual data and analytical methodologies

Pompe disease is a rare (approximately 1 in 40,000 births), inherited condition. It is considered a lysosomal storage disorder because people with Pompe have lysosomes (the recycling center of each cell) that cannot break down certain types of complex sugars. Pompe disease is caused by mutations in a gene that make an enzyme called acid alpha-1, 4-glugosidase ("GAA") or acid maltase. Normally, the body uses GAA to break down glycogen, a stored form of sugar used for energy. The GAA gene is responsible for making this enzyme. Without the proper function of GAA, glycogen that enters into the lysosome is not broken down, but continues to build up and disrupts the functioning of cells. Excessive amounts of lysosomal glycogen accumulate everywhere in the body, but the cells of the heart and skeletal muscles are

the most seriously affected.

The Secretary's Advisory Committee on Newborn Screening recommended to the Department to add Pompe Disease to the list of congenital disorders for which newborns must be screened, and the Department concurred with the recommendation. It was determined that Pompe Disease met the criteria under s. DHS 115.06 for being added to the list of congenital disorders for which the WSLH must test the blood samples of newborns.

Analysis and supporting documents used to determine effect on small business
None, the proposed rule will not have an effect on small businesses.

Effect on small business
The proposed rule will not have an effect on small businesses.

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/active-rulemaking-projects.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. DHS 115.04 (17) is created to read:

DHS 115.04 (17) Pompe Disease, ICD-10-CM-E74.02.

SECTION 2. EFFECTIVE DATE. This rule 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.