WISCONSIN DEPARTMENT OF HEALTH SERVICES
PROPOSED ORDER TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services proposes an order to **renumber and amend** DHS 115.055; **amend** DHS115.04 (8) (b), (13), (15) (c), (e) and (i); **repeal and recreate** DHS 115.04 (17); and **create** DHS 115.04 (13m), (18), and 115.055 (1), relating to screening of newborns for congenital disorders.

RULE SUMMARY

Statutes interpreted
Not applicable.

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

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

Section 253.13 (2), Stats., authorizes the department to impose a fee, by rule, that is sufficient to pay for all of the following:

1. The cost of testing newborns for the congenital disorders provided by the Wisconsin State Laboratory of Hygiene ("WSLH").
2. Funding services, including follow-up diagnostic services, physician prescribed special dietary treatment and follow-up counseling to the patient and the patient's family.
3. Periodic evaluation of infant screening programs.
4. The costs of consulting with experts in reviewing and evaluating the program.
5. The costs of administering the newborn hearing screening required under s. 253.115, Stats.
6. The costs of the department to administer the congenital disorder program.

The department is required to credit the amounts received to appropriations accounts under s. 20.435 (1) (ja) and (jb), Stats. The congenital disorder program (newborn screening program) includes newborn critical congenital heart disease (CCHD) screening.

Related statute or rule
Section 253.115, Stats.
42 USC 330b-8 to 300b-17.

Plain language analysis
First, the proposed rules seek to add the following conditions to the panel of congenital and metabolic disorders for which newborns shall be tested as listed in s. DHS 115.04 and in accordance with s. 253.13 (1), Stats.:

— X-Linked Adrenoleukodystrophy ("X-ALD"), which is a rare genetic condition caused by a change in a gene so that a protein which helps the body break down certain types of fats is not made correctly. It affects both males and females, but females tend to develop symptoms as adults and the symptoms are often milder than those seen in males. Males with X-ALD are often normal in infancy, but they may go on to develop problems with their adrenal glands which produce hormones, brain and spinal cord. Without treatment, these boys may become seriously ill or develop irreversible neurologic damage during childhood. Treatments for X-ALD include providing hormones that are deficient. Another treatment, hematopoietic stem

cell transplantation may halt progressive brain abnormalities. There is no cure for X-ALD, but early diagnosis following newborn screening means that children with X-ALD can often avoid serious hormone insufficiency, degenerative brain disease, and death by having regular monitoring to detect hormonal and brain abnormalities at early stages when treatment is most likely to be effective. Nearly all adult males and some women with X-ALD not treated early will develop stiffness in their legs and difficulty walking.

— Mucopolysaccharidosis type I ("MPS I"), which is an autosomal recessive lysosomal disease (LD) affecting an estimated 1 per 100,000 newborns. MPS I can be generally classified into two forms, severe and attenuated, based on the age of onset and severity. Severe MPS I has a chronic and progressive disease course involving multiple organs and causes joint disease, cardiorespiratory compromise, and death typically by 18 months without treatment. Attenuated MPS I exhibits similar symptoms; however, the rate of progression and severity of complications is delayed and patients rarely show neurological involvement beyond learning disabilities. Specific treatments include enzyme replacement therapy ("ERT") and hematopoietic stem cell transplantation ("HSCT"). ERT is the mainstay of treatment for the attenuated form. However, HSCT, which allows for endogenous production of the missing enzyme, is used in the severe form because intravenous ERT does not penetrate the blood-brain barrier. Early presymptomatic detection of MPS I via newborn screening may result in improved neurocognitive outcomes through earlier enzymatic replacement therapy (ERT) and hematopoietic stem cell transplant (HSCT), even though improvement in mortality has not been established. Diagnosis is based on clinical findings, additional biochemical tests, and mutation analysis.

These conditions were recommended for addition in the rule by the Wisconsin Newborn Screening Program ("NBS") and the Secretary's Advisory Committee on Newborn Screening ("SACNBS"). Based upon those recommendations, former Secretary-designee Timberlake approved adding X-ALD and Secretary-designee Johnson approved adding MPS I to the newborn screening panel.

Second, the proposed rule aims to amend the screening sample collection card fee in s. DHS 115.055. 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., those entities purchase newborn screening sample collection cards from the WSLH and return the collection card with the newborn's blood sample to WSLH to test for each of the conditions specified by the department under s. DHS 115.04. The cost of each collection card constitutes the fee for testing, follow-up services, and administration provided in s. 253.13 (2), Stats. 2023 Wis. Act 19 amended s. 253.13 (2), Stats., to read that beginning on July 7, 2023, the fee imposed cannot be less that $195. The Department is currently complying with the statute and charging $195, but Section DHS 115.055 currently lists the fee as $109.

In addition to conforming with the $195 fee provided in the statute, the department proposes to increase the fee for testing to $223 with ongoing biennial adjustments based on the average three-year Medicare Economic Index ("MEI"). Although the cost of testing was increased to $195 by statute effective July 7, 2023, the addition of X-ALD and MPS I as proposed in this rule would increase the cost of testing by $12 per infant. Each year, as more children test positive for metabolic disorders, more individuals are added to the NBS's case load and require ongoing follow-up services and treatment, and the costs of those services will continue to increase year over year. Because the $109 fee in s. DHS 115.055 has not been updated since 2010, the program has been operating at a loss for several years and accumulated a deficit. Furthermore, the fee provided under s. 253.13 (2) should include the cost of administering the newborn hearing screening program under s. 253.115, Stats., but that program has not been funded by fees and has relied on federal grant money to operate. The increase to $223 will account for all current costs for the

program. The MEI is a trusted tool for capturing staffing, equipment, and general practice costs increases within the medical industry.[1] Allowing biennial increases based on the MEI will cover the added costs of testing for newer conditions, fund the newborn hearing screening program, and provide funds sufficient to pay for services based on NBS and WSLH projections for collection card volumes and programmatic costs in the coming years—thereby avoiding future deficits in administration of the program.

Finally the department seeks to revise outdated or erroneous provisions, and correct any spelling or grammatical errors in the current version of the rule. There are two conditions, hypermethioninemia ("MET") and trifunctional protein deficiency ("TFP"), which were previously approved for screening and were mistakenly left out of past rulemaking. The Department proposes to add these conditions to the list of conditions in s. DHS 115.04.

Summary of, and comparison with, existing or proposed federal regulations
There are no federal laws or regulations that require newborn screening independent of state law, but the Secretary of the Department of Health and Human Services ("HSS") maintains a standardized list of disorders known as the Recommended Uniform Screening Panel ("RUSP"). The RUSP lists conditions that have been supported by the Advisory Committee on Heritable Disorders in Newborns and Children and recommended by the Secretary of HHS.

Comparison with rules in adjacent states
Illinois, Iowa, Michigan and Minnesota require newborns to be screened for congenital and other disorders, and the provision of other services and programs. Similar to Wisconsin, these states impose a fee for the screening and other services. However, each state differs in the disorders screened and related services provided, so it is not possible to directly compare the fee in Wisconsin with the fees in other states.

Illinois:

Illinois's Department of Public Health assesses institutions or persons submitting a sample for newborn screening. There is a fee of $128 which may be increased if screening for additional disorders. Statements are mailed on a monthly basis to facilities submitting specimens for analysis. Payment is required upon receipt of the statement. 77 Ill. Adm. Code 660.70. Illinois's Newborn Metabolic Screening Act 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, and this process is similar to Wisconsin's procedure for adding disorders to the screen. Illinois 410 ILCS 240/1.10 (b); 77 Ill. Adm. Code 661.10. In 2015, Illinois added MPS-1 to their screening panel of conditions. In 2019, Illinois added X-ALD to the screening panel of conditions. Illinois screens for 36 of the 37 core conditions on the RUSP.

Iowa:

Iowa's Department of Public Health assesses a fee of $122 for activities associated with the Iowa Newborn Neonatal Metabolic Screening Program. Included in the fee is an amount to fund a program for eligible individuals with certain inherited diseases identified through the program who may be unable to pay the fee. The Department of Public Health is required to review and determine the fee annually. 641 IAC 4.3(9) A proposed fee increase is currently under review. Iowa Code s. 136A.5A 641—4.3(136A). In 2023, Iowa added MPS 1 to their screening panel of

[1] The Medicare Economic Index is authorized under 42 USC 1395u (b) (3), which states that states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes. The Centers for Medicare and Medicaid Services develop and update the Medicare Economic Index, expressed as a percentage. *See* 42 CFR 405.409 (d); 87 Fed. Reg. 45860 (July 29, 2022), available at https://www.federalregister.gov/documents/2022/07/29/2022-14562/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other.

conditions. Iowa is currently pursuing implementation of X-ALD and is conducting a pilot study. Iowa screens for 34 of the 37 core conditions on the RUSP.

Michigan:

Michigan's fee for screening newborns and other services are established under MCLS s. 333.5431(4) by annual adjustment based on the cumulative annual percentage change in the Detroit Consumer Price Index. The current fee amount is $135.29. Under MCLS s. 333.5430 (3), the newborn screening quality assurance advisory committee must conduct a financial review of any recommended changes to the list of newborn screening tests and make a recommendation to increase or decrease in the amount charged pursuant to section 5431 for newborn screening tests. The recommended change is limited to any net change in the amount of the actual cost of any proposed additional tests and follow-up minus savings from any proposed deleted tests and follow-up. Michigan includes 56 disorders in its screening panel, and MCLS 333.5430 establishes an advisory committee that meets annually to consider adding disorders to the screen and approve fee increases based on adding a disorder. In 2017, Michigan added MPS-1 to its screening panel. In 2019, Michigan added X-ALD to its screening panel. Michigan screens for 36 of the 37 core conditions on the RUSP.

Minnesota:

Minnesota Statutes specify the fee to be charged for newborn screening. Section 144.125 subd. 1.(c) of the Minnesota Statutes provides a base fee of $177 per specimen, plus a fee of $15 per specimen to offset the cost of hearing and intervention services under Minn. Stat. s. 144.966. Section 144.064 subd. 3.(d) further provides a $43 fee increase to test for human herpesvirus cytomegalovirus. Thus, the total fee per specimen is $235. Unlike Wisconsin, Minnesota does not pay for special dietary treatment, genetic counseling, or diagnostic or clinical services, and the $235 per specimen fee does not include those additional services. The list of tests performed in Minnesota may be revised if recommended by the advisory committee established under Minn. Stat. s. 144.1255 and approved by the Commissioner of the Minnesota Department of Health. Revisions are exempt from the rulemaking requirements in chapter 14 of the Minnesota Statutes. Minn. Stat. s. 144.125 subd. 2. Minnesota added MPS-1 and X-ALD to its screening panel in 2017. Minnesota screens for 35 of the 37 core conditions on the RUSP.

Summary of factual data and analytical methodologies

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, NewSTEPS https://www.newsteps.org/data-center/state-profiles?q=data-resources/state-profiles.

— The Wisconsin Newborn Screening Program DHS Newborn Screening program paper, and WSLH Surcharge Report 2022. These documents summarize that WSLH costs for the NBS Program include: the costs of purchasing, storing, and distributing the collection cards; laboratory equipment, consumables, and staff salaries to perform the testing; short term follow-up of all non-normal results reported by the laboratory; and education activities for health care providers regarding newborn screening issues such as specimen collection and reporting of test results. The cost of NBS laboratory operations consistently increases due to program expansion, enhancements and inflation. The paper reports that the WSLH typically experiences an inflation rate of 3% annually, and addition and implementation of new conditions to the panel also increases costs due to a variety of reasons such as additional equipment, staff time to run additional tests, and new test set up.

— DHS NBS program reports, which indicate that costs to the department are based on the number of participants in NBS, diagnostic and counseling services (i.e. clinical assessment, nutritional and genetic counseling); special dietary treatment (i.e. coordinating payment of specialty formula and vitamins); consulting with experts (i.e. hosting and coordinating the newborn screening advisory group meetings) and management and supplies for hearing screening and Critical Congenital Heart Disease (CCHD) screening. Heart and hearing screening are run by DHS staff and contracted agencies, while the blood screening is run by DHS staff and contracted agencies along with the WSLH. These reports also indicate that each child with a positive screening result gets a confirmatory test in a specialty center and receives the necessary dietary treatment for life; thus, as children live longer and the cumulative number of patients increases, the overall cost of the program rises. The report also finds that the costs for formula and other food products have risen as much as 20% annually, and the total number of the patient population served by the NBS program nearly doubled from fiscal year 2009 to 2022.

Analysis and supporting documents used to determine effect on small business
According to the WSLH Surcharge Report, the number of newborn screening sample cards purchased in SFY 2022 was 59,737. In FY 2024, 2025, and 2026 it is estimated that there will be approximately 55,000 blood cards purchased annually by hospitals and midwives. Hospitals do not meet the definition of a "small business" under s. 227.114 (1), Stats., but midwives do. Midwives purchase approximately 3% of the estimated 55,000 cards, or 1,650 cards in total. The number of cards may fluctuate slightly in future years depending on factors such as the number of births or cards purchased each year.

The $28 fee increase as a result of the proposed rules may have a moderate economic impact on midwives. Midwives' small businesses are affected by an increase in the blood collection card fee as they purchase cards out of pocket for their patients. (2023 Memorandum of Understanding Fee-exempt Newborn Screening Blood Collection Cards). The total annual amount estimated for all midwives as a result of the proposed rule is approximately $46,200—which is 3% of increased cost for 55,000 cards as a result of the proposed rule. Purchasers of newborn screening sample collection cards may seek reimbursement of the costs of the newborn screening sample cards and any related costs incurred from private insurers, Medicaid, parents of newborns, or the NBS Program for eligible parents.

The department published a solicitation in the Administrative Register, requesting comments on the economic impact of the proposed rule, from December 18, 2023 to January 17, 2024.

Effect on small business
The fee increase in the proposed rule may have a moderate economic impact on small business. All other changes in the proposed rule will not have an effect on small businesses.

Agency contact person
Tami Horzewski MS, CHES
Newborn Screening Program Coordinator
Bureau of Community Health Promotion, Division of Public Health
Wisconsin Department of Health Services
608-266-8904
Tami Horzewski@dhs.wisconsin.gov

Statement on quality of agency data
The data used by the department to prepare these proposed rules and analysis comply with s. 227.14 (2m), Stats.

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 (8) (b) and (13) amended to read:

DHS 115.04 (8) (b) Long−chain L−3−Hydroxy acyl−CoA dehydrogenase deficiency, trifunctional protein deficiency, ICD−10−CM−E71.318.

DHS 115.04 (13) Argininosuccinic ~~acidura~~ aciduria, ICD-10-CM-E72.22.

SECTION 2. DHS 115.04 (13m) is created to read:

DHS 115.04 (13m) Hypermethioninemia (MET) ICD-10-CM- E72.19.

SECTION 3. DHS 115.04 (15) (c), (e), and (i) are amended to read:

DHS 115.04 (15) (c) Methylmalonic acidemia ~~(CBL A, B, C, D; MUT)~~ (cobalamin disorders) and methylmalonyl-CoA mutase deficiency, ICD−10−CM−E71.120.

DHS 115.04 (15) (e) ~~3 Methylcrotonyl CoA carboxylase deficiency~~ 2-Methyl-3-hydroxybutyric aciduria, ICD-10-CM-E71.19

DHS 115.04 (15) (i) ~~2 Methyl 3 hydroxbutyric aciduria~~ 3-Methylcrotonyl-CoA carboxylase deficiency, ICD-10-CM-E71.19.

SECTION 4. DHS 115.04 (17) is repealed and recreated to read:

DHS 115.04 (17) Lysosomal disorders, including all of the following:
a) Pompe Disease ICD−10−CM−E74.02
b) Mucopolysaccharidosis I ICD-10-CM-E76.0

SECTION 5. DHS 115.04 (18) is created to read:

DHS 115.04 (18) X-Linked Adrenoleukodystrophy (X-ALD), ICD-10-CM-E71.52

SECTION 6. DHS 115.055 is renumbered DHS 115.055 (2) and amended to read:

DHS 115.055 (2) CALCULATION OF FEES. The newborn screening sample collection card fee for testing a newborn under s. 253.13 (1), Stats., and this chapter shall be ~~$109~~ $223 as of [LRB to insert effective date of rule] to cover the costs of testing and to fund follow−up services and other activities under s. 253.13 (2), Stats. Thereafter, the fee charged under this section shall be adjusted by the department on July 1 of each odd numbered year based on the average of the three most recently published Medicare economic indexes.

SECTION 7. DHS 115.055 (1) is created to read:

DHS 115.055 (1) DEFINITION. In this section, "Medicare economic index" means the price index authorized under 42 USC 1395u (b) (3), and computed and published in accordance with 42 CFR 405.504 (d).

SECTION 8. EFFECTIVE DATE. This rule takes effect on the first day of the month following publication in the Wisconsin Administrative Register as provided in s. 227.22 (2) (intro.), Stats.