

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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| <b>1. Type of Estimate and Analysis</b><br><input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected  | <b>2. Date</b><br>2/20/2024   |
| <b>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)</b><br>Chapter DHS 115, relating to screening of newborns for congenital disorders.   |   |
| <b>4. Subject</b><br>Adding new conditions to the list of conditions tested in s. DHS 115.04; Increasing the fee to fund the services permitted under s. 253.13(2), Stats; revising outdated and erroneous provisions throughout the rule.   |   |
| <b>5. Fund Sources Affected</b><br><input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S  | <b>6. Chapter 20, Stats. Appropriations Affected</b><br>Sections 20.435(1)(ja) and (jb), and 20.285(1)(i), Stats. |
| <b>7. Fiscal Effect of Implementing the Rule</b><br><input type="checkbox"/> No Fiscal Effect <input checked="" type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs<br><input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget   |   |
| <b>8. The Rule Will Impact the Following (Check All That Apply)</b><br><input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors<br><input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers<br><input checked="" type="checkbox"/> Small Businesses <b>(if checked, complete Attachment A)</b>  |   |
| <b>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).</b><br>\$1,540,000 based on the increased card fee as a result of the proposed rule. Businesses who purchase cards at the increased rate will be reimbursed for a portion of the cost of purchasing a card when the individual giving birth is covered by private insurance or Medicaid. Biennial increases to fees based on the three-year Medicare Economic Index (MEI) are estimated between \$3 and \$6 per card, and a portion of that increase can similarly be reimbursed through private insurance or Medicaid.  |   |
| <b>10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?</b><br><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  |   |
| <b>11. Policy Problem Addressed by the Rule</b><br>Section. 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 WSLH. Conditions which are tested for are provided in s. DHS 115.04. The list in s. DHS 115.04 does not include X-ALD and MPS 1, both of which were approved for inclusion in the rule in accordance with s. DHS 115.06. Additionally, Hypermethioninemia (MET) and Trifunctional Protein Deficiency (TFP) were approved, respectively, in 2000, and 2003—when the process for adding conditions was different—and were mistakenly left off the list of tested conditions. All four of these conditions should be added to s. DHS 115.04.<br><br>The fee for testing as provided in s. DHS 115.055 is currently listed as \$109, and this fee does not reflect the minimum allowable fee following 2023 Wis. Act 19. Section 253.13 (2), Stats., states that, as of July 7, 2023, “the fee imposed by the department . . . cannot be less than \$195.” At minimum, the rule must be updated to reflect the \$195 fee that is being charged in accordance with the statute.<br><br>An additional increase from \$195 to \$223 is proposed to address additional costs and services that should be included in the fee under s. 253.13 (2), Stats., but have been un- or under-funded since the fee was last updated. Testing for X-ALD and MPS I will cost an additional \$12 per card. Each year, more children test positive for metabolic disorders and more individuals are added to the NBS’s case load and require ongoing follow-up services and treatment, and the fee has not risen commensurate with the increased costs of those services, and the program has been operating at a loss for several years. Additionally, s. 253.13 (2) requires that the fee charged shall fund the newborn hearing screening program, but the |   |

## **ADMINISTRATIVE RULES**

### **Fiscal Estimate & Economic Impact Analysis**

fee charged has been insufficient to fund that program and the department has relied on federal grant money to operate. The increase from \$195 to \$223 for the fee will account for all additional costs as a result of the proposed rule, and allow all programs which are supposed to be funded by the fee to operate as intended.

Finally, the proposed rule seeks to account for ongoing increases in the volume of services provided and the cost of those services by allowing the department to increase the fee charged on a biennial basis based on the average MEI of the three preceding years. The MEI is a trusted tool for capturing staffing, equipment, and general practice costs increases within the medical industry. 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.

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12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.

From December 18, 2023, to January 17, 2024, the Department solicited information and advice from individuals, businesses, associations representing businesses, and local governmental units who may be affected by the proposed rule for use in analyzing and determining the economic impact that the rules would have on businesses, individuals, public utility rate payers, local governmental units, and the state's economy as a whole. One public comment was received and concern regarding the fee increase was expressed.

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13. Identify the Local Governmental Units that Participated in the Development of this EIA.

None – the proposed rule is not expected to affect local governmental units.

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14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

As stated in section 11. of this analysis, s. 253.13, Stats., currently requires that, as of July 7, 2023, the department charge no less than \$195 in fees to fund testing, dietary and follow-up counseling and services, and for administering the hearing screening program under s. 253.115, Stats. Based on that express directive in statute, the department began charging a fee of \$195 on July 7, 2023. See also *Debeck v. Wis. Dep't of Nat. Res.*, 172 Wis. 2d 382, 388 (Ct. App. 1992) (“When a conflict occurs between a statute and a rule, the statute prevails.”). Accordingly, the increase from \$109 to \$195 was a result of statute--not the proposed rule--and the increase from \$109 to \$195 was therefore not considered in the department's analysis under ss. 227.137 (3) (b) 2. and 227.139, Stats., as both of those statutes require the department to consider implementation and compliance costs that incurred or passed along to businesses, local governmental units, and individuals over “any 2-year period as a result of the proposed rule.”

The department considered the economic impact of the increases as a result of the proposed rule- namely the increase from \$195 to \$223, and potential biennial increases to the fee based on the three-year average of the MEI. According to a surcharge report from the Wisconsin State Lab of Hygiene (WSLH), it is estimated that approximately 55,000 testing cards will be purchased annually in 2024, 2025, and 2026. By raising \$28 per card, the estimated total additional cost for purchasing 55,000 under the proposed new rule would be \$1,540,000. A portion of those increased costs would be reimbursed through individuals giving birth who are covered by private insurance or Medicaid.

The proposed rule would also require the department to adjust the fee on July 1 of every odd-numbered year based on the average of the three most recently published MEIs. As explained in section 11. of this analysis, the MEI captures staffing, equipment, and general practice costs increases within the medical industry. If the fee were to increase on July 1, 2025, the three most recently published MEIs are 3.8 percent (in 2023), 2.1 percent (in 2022), and 1.4 percent (in 2021) – which averages out to 2.4 percent. A 2.4 percent increase to the \$223 fee would approximately \$5.35 per card, or an additional total cost of \$294,360 per year based on an estimated 55,000 cards purchased. Although the department cannot predict the exact estimates of future MEIs, the department calculated the following based on annual MEIs

## **ADMINISTRATIVE RULES**

### **Fiscal Estimate & Economic Impact Analysis**

published from 2003 to 2023: an average of 1.74 percent; a median of 1.5 percent; a range from .4 percent (2011) to 3.8 percent (2023); and a mode of .8 percent (2013–2015). Based on these numbers, the department estimates that the biennial fee increases will vary from approximately 1.5 to no more than 4 percent.

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#### 15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The proposed fee increase will cover increased costs experienced by both WSLH and the department, both of which operated at a loss for several years when the fee charged was \$109. Additionally, the increased revenue from fees collected will ensure that the department and the WSLH are able to adequately test for all conditions, and any future conditions added to the rule in accordance with s. 253.13 (1), Stats. These revenues will allow the department to continue to provide all of the following to children who test positive for conditions listed in the rule: (1) Necessary diagnostic services; (2) Special dietary treatment as prescribed by a physician; (3) follow-up counseling for the child and the child’s family. Increased revenues will also permit the department and WSLH to administering the program, conduct periodic evaluations of infant screening programs, and the costs of consulting with experts in reviewing the program in accordance with s. 253.13 (5), Stats. As noted above, all of these services and programs should be covered by the fee under s. 253.13(2), Stats.

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#### 16. Long Range Implications of Implementing the Rule

Long range implications include decreasing negative health outcomes for infants with X-ALD and MPS 1. Early interventions are available 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. Each child with a positive screening result gets a confirmatory test in a specialty center and receives the necessary dietary treatment for life if applicable; thus, as children live longer and the cumulative number of patients increases, the overall cost of the program rises. DHS reports find 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. The proposed fee increase will cover the increased costs experienced by both the WSLH and the Department.

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#### 17. Compare With Approaches Being Used by Federal Government

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. The Wisconsin NBS program currently screens for 33 of the 37 conditions on the RUSP. If the proposed rule takes effect, the program would be screening for 35 of the 37 RUSP conditions.

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#### 18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois’s Department of Public Health assesses 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’s Department of Public Health assesses a fee of \$162 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). Iowa Code s. 136A.5A 641—4.3(136A). In 2023, Iowa added MPS 1 to their screening panel of 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.

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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 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.

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

### ATTACHMENT A

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

The majority of the estimated 55,000 cards purchased are purchased by hospitals, which do not meet the definition of "small business" under s. 227.114 (1), Stats. Approximately 3% of the estimated 55,000 cards purchased in Wisconsin are purchased by midwives, who likely meet the statutory definition of small businesses.

In section 14 of the economic impact analysis, the department estimated \$1,540,000 in increased compliance costs as a result of increasing the fee from \$195 to \$223. The amount of that total attributable to all midwifery businesses in Wisconsin would be approximately \$46,200.

Section 14 also estimated a hypothetical 2025 increase based on prior MEIs of \$5.35 per card, or \$294,360 additional dollars per year in from July 1, 2025 to June 30, 2026. The amount of that total attributable to midwifery businesses in Wisconsin would be approximately \$8,830.80.

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

The department relied on NBS program reports to identify the costs for testing and administering the program in years past. These reports 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.

The department relied on data from the WSLH's surcharge report to estimate the number of cards purchased in 2024 through 2026, and the percentage attributable to midwifery businesses. This report also summarize WSLH costs for the NBS Program, including: 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.

The department reviewed final rules from the Centers for Medicare & Medicaid Services (CMS) and CMS publications to identify annual MEIs from 2003 to 2023.

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

- Exemption of Small Businesses from some or all requirements  
 Other, describe:

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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

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.

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5. Describe the Rule's Enforcement Provisions

There are no enforcement provisions in the proposed rule. Testing is required under s. 253.13, Stats.

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6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes     No
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