

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<p>1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected</p>	<p>2. Date 05/21/2021</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) DHS 115, relating to screening of newborns for congenital disorders.</p>	
<p>4. Subject Addition of Pompe disease to the screening of newborns for congenital disorders.</p>	
<p>5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S</p>	<p>6. Chapter 20, Stats. Appropriations Affected N/A</p>
<p>7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget</p>	
<p>8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)</p>	
<p>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$ 671,100 implementation cost for the Wisconsin State Lab of Hygiene (WSLH)</p>	
<p>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)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule 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 WSLH. 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. The Department intends to revise ch. DHS 115 to conform the rule language to s. 253.13, Stats. The proposed rule order adds Pompe disease as a condition for which newborns must be tested.</p>	
<p>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 April 19, 2021 to May 3, 2021, 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. Three public comments were received, they did not list any economic impact and the comments were in support of adding Pompe as a condition for which newborns must be tested.</p>	
<p>13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.</p>	
<p>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) For the implementation of screening for Pompe, there is a cost of \$11.00 per infant screened per approximately 61,000 WI births annually. The additional cost is attributed to WSLH operational costs for instruments, reagents and consumables, and laboratory staff time for the following: testing, result review and reporting, and program follow up activities on screening positive cases. The cost for follow up counseling is indeterminate. There is no cost for special dietary treatment.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule</p>	

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There are no alternatives to rulemaking. Preservation of the public health and welfare requires screening newborns for Pompe Disease.

16. Long Range Implications of Implementing the Rule

Long range implications include decreasing negative health outcomes for infants with Pompe. 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 this disorder.

17. Compare With Approaches Being Used by Federal Government

There appears to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rules.

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

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 has been screening for Pompe Disease since 2015.

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 Pompe Disease.

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 Pompe Disease. 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 Pompe Disease since 2017.

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 has been screening for Pompe Disease since 2017.

19. Contact Name

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20. Contact Phone Number

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ATTACHMENT A

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)

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

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

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

5. Describe the Rule's Enforcement Provisions

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

- Yes No
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