

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 21-051

Ch. DHS 115.04 (17)

Basis and Purpose of Proposed Rule

Permanent rule to propose amendments to DHS 115.04 (17), relating to screening of newborns for congenital disorders. The proposed rule order adds Pompe disease as a condition for which newborns must be tested.

Department Response to Legislative Council Rules Clearinghouse Recommendations

Legislative Council did not recommend any changes to the proposed rule.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

None

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

N/A

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

N/A

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

N/A

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

N/A

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

None

Fiscal Estimate/Economic Impact Analysis

None

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department's Administrative Rules Website on September 20, 2021. A public hearing was held on October 5, 2021, in a Zoom virtual public hearing. Public comments on the proposed rule were accepted until October 5, 2021 at 4:00 pm.

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

Registrant	Position Taken (Support or Opposed)
Ryan Colburn	Support
Stephanie Clubb	Support

Summary of Public Comments to the Proposed Rule and the Agency’s response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

Rule Provision	Public Comment	Department Response
DHS 115.04	Twenty commenters from various states shared their gratitude for newborn screening for Pompe and the positive impact this had on their child or a child they know who was diagnosed with Pompe. These commenters support the proposed rule.	No modification to the proposed rule order necessary.
DHS 115.04	Fifteen commenters indicated the importance of early detection and intervention in preventing serious health consequences and support the proposed rule.	No modification to the proposed rule order necessary.
DHS 115.04	Eight commenters indicated that they wished Pompe screening was in place when they were younger so they could have had a proper diagnosis, been aware of their late onset Pompe condition, and/or been aware they were a carrier. These commenters support the proposed rule.	No modification to the proposed rule order necessary.
DHS 115.04	Two commenters shared that the delay in getting their baby screened and diagnosed with Pompe has caused life-long repercussions for their child and hope screening will prevent these life-altering circumstances happening to other children. These commenters support the proposed rule.	No modification to the proposed rule order necessary.

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		X	
Department response to Rules Clearinghouse recommendations	X		
Final Regulatory Flexibility Analysis	X		
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis			X
Public Hearing Summary	X		
List of Public Hearing Attendees and Commenters	X		
Summary of Public Comments and Department Responses	X		
Fiscal Estimate/Economic Impact Analysis		X	
Revised Fiscal Estimate/Economic Impact Analysis			X
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			X
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			X
DOA report under s. 227.137 (6), Stats., on rules with economic impact of \$20 MM or more			X
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			X