

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

X Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

DHS 115, Screening of Newborns for Congenital and Metabolic Disorders

3. Subject

Newborn screening for congenital and metabolic disorders (to add Critical Congenital Heart Disease (CCHD) and Organic Acidemias (OAs) as conditions for which newborns must be tested. Currently, the conditions listed in s. DHS 115.04, are coded using the *International Classification of Diseases, 9th Revision* (ICD-9CM). The U.S. Department of Health and Human Services requires health care providers, health plans, and health care clearinghouses to transition to the *International Classification of Diseases, 10th Revision* (ICD -10 CM) effective October 1, 2015. To ensure consistency among health care providers and to facilitate the transition in this order, the proposed rule lists the ICD-10 CM codes for the CCHD and OA conditions proposed, and the conditions already listed in s. DHS 115.04.

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

6. Fiscal Effect of Implementing the Rule

X No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes X No

9. Policy Problem Addressed by the Rule

As provided in s. 253.13 (1), Stats. (2011-12), ch. DHS 115 specifies the congenital and metabolic orders 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 that the required screening may be performed by methods in addition to blood testing. Under the permanent order, the department revises ch. DHS 115 to conform the rules to s. 253.13, Stats., and adds CCHD and OA as conditions for which newborns must be tested and the ICD-10 CM codes for CCHD and OA conditions proposed, and the conditions already listed in s. DHS 115.04.

CCHD is usually described as those congenital cardiac malformations in which surgical or catheter-based therapy is necessary within the first months of life, and is screened for by use of pulse oximetry. In September 2010, the federal Department of Health and Human Services' Discretionary Advisory Committee on Heritable Disorders in Newborns and Children added CCHD to its Recommended Uniform Screening Panel Core Conditions. To date, 35 states have added CCHD screening to their newborn screening panel.

Adding OA as a condition for testing corrects an inadvertent omission from the list of congenital and metabolic disorders. OA is a group of inherited disorders that lead to an abnormal buildup of particular acids known as organic acids in the body for which the WSLH currently tests newborns. Though OA met the criteria under s. DHS 115.06 for being added to the list of congenital and metabolic disorders for which WSLH must test blood samples, the disorders were not included in subsequent revisions of s. DHS 115.04.

The department solicited public comments on the rule's economic impact December 2, 2014 to December 16, 2014. No

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comments were received.

The department does not anticipate that the revisions to ch. DHS 115 will have a fiscal impact on the department or local government.

10. 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.

The proposed rule will not have an effect on small businesses, as defined under s. 227.114 (1), Stats.

11. Identify the local governmental units that participated in the development of this EIA.

The proposed rule will not have an effect on small businesses, as defined under s. 227.114 (1), Stats.

12. 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)

The proposed rule will not have an effect on small businesses, as defined under s. 227.114(1), Stats.

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

Section 253.13 (1), Stats., requires that every infant born in each hospital or maternity home, prior to its discharge, be tested for congenital and metabolic disorders, as specified in rules promulgated by the department. Therefore, there are no reasonable alternatives to the proposed rulemaking.

14. Long Range Implications of Implementing the Rule

Indeterminate.

15. 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.

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

Illinois, Iowa, Michigan, and Minnesota state law require that newborns be screened for congenital and metabolic disorders, including CCHD and Organic Acidemias.

17. Contact Name

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18. Contact Phone Number

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This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
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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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