

**ADMINISTRATIVE RULES
FISCAL ESTIMATE AND
ECONOMIC IMPACT ANALYSIS**

Type of Estimate and Analysis

Original Updated Corrected

Administrative Rule Chapter, Title and Number

DHS 115, Screening of Newborns for Congenital and Metabolic Disorders

Subject

A fee for screening newborns for congenital and metabolic disorders and other services.

Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

Chapter 20 , Stats. Appropriations Affected

Fiscal Effect of Implementing the Rule

<input checked="" type="checkbox"/> No Fiscal Effect	<input type="checkbox"/> Increase Existing Revenues	<input type="checkbox"/> Increase Costs
<input type="checkbox"/> Indeterminate	<input type="checkbox"/> Decrease Existing Revenues	<input type="checkbox"/> Could Absorb Within Agency's Budget
		<input type="checkbox"/> Decrease Costs

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

<input type="checkbox"/> State's Economy	<input type="checkbox"/> Specific Businesses/Sectors
<input type="checkbox"/> Local Government Units	<input type="checkbox"/> Public Utility Rate Payers

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

Yes No

Policy Problem Addressed by the Rule

The legislature under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32, directs the department to impose by rule, a fee sufficient to pay for: 1) the cost of testing newborns for the congenital and metabolic disorders provided by the Wisconsin State Laboratory of Hygiene (WSLH); 2) to fund 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.; and 6) the costs of the department to administer the congenital disorder program.

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)

Since 2010, the WSLH has imposed a fee of \$109 by policy to pay for the testing and services mandated under s. 253.13 (2), Stats. The fee in the proposed rules is unchanged from the current amount being imposed for testing and other services. As a result, the department does not expect any additional implementation or compliance costs to be incurred by purchasers of newborn sample screening cards. Because there are no new or changed conditions and no estimated increased or decreased costs that would occur if the \$109 fee amount is codified in administrative rule, the rule will not have an economic impact on businesses, business sectors, local governmental units, public utility rate payers or the state's economy as a whole.

For increased public participation in the rule, the department established an advisory committee that included representatives from private hospitals, statewide health provider organizations, the State Laboratory of Hygiene, Universities, statewide consumer organizations, local public health

departments, and a consumer of the Newborn Screening Program services to help draft the rule and summary (analysis). The majority of the comments (and questions) received from advisory committee members was on the manner and substance of the rule's summary (analysis), including requesting additional information about the newborn screening programs in adjacent states and their program costs. Other comments concerned the reimbursement rate of the fee by the Medicaid program. No member of the advisory committee commented on the fee amount. In response to advisory committee comments, the department made changes to the summary (analysis) by adding additional information on newborn screening programs of neighboring states, accurately describing program costs, and explaining the newborn screening program in greater detail. Also, a second paragraph within the text of the permanent rule was removed after a committee member questioned the purpose and suggested it was not needed. Because the reimbursement rate of the Medicaid program is not germane to the codification of the fee for screening and other services for congenital and metabolic disorders in administrative rules, the department does not address that matter in this analysis.

On January 23, 2012, the department began soliciting information and advice as required under s. 227.137, Stats., and Executive Order #50, to help prepare this economic impact analysis. The comment period ended on February 6, 2012.

Four persons provided comments in response to the department's solicitation. The first comment emphasized the importance of the program and expressed support for sustainable funding of the program. The second comment was a question about whether Amish midwives are charged fees for newborn screening cards. The third comment suggested edits to the explanation of the rule and increased specificity in the language related to counseling services and follow-up. The fourth comment expressed concerns about program sustainability under the current structure, sufficiency of Medicaid reimbursement of the fee, opportunity to explore alternative options to the current fee of \$109, as well as asked if consideration would be given to decrease the current fee by 10% because the fee was not based on program costs.

There were no comments received from businesses, associations representing businesses, local governmental units, or individuals that suggest that the existing fee being codified in rule would adversely affect, in a material way, such businesses, business sectors, local governmental units, individuals, the economy, productivity, jobs, or the overall competitiveness of the state.

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

The benefits of implementing the fee by rule is compliance with s. 253.13 (2), Stats. The alternative to implementing the fee by rule is noncompliance with the legislated directive in s. 253.13 (2), Stats., to impose the fee for the screening and other services by rule.

Long Range Implications of Implementing the Rule

There are no known long range implications of implementing the rule.

Compare With Approaches Being Used by Federal Government

There appear to be no existing or proposed federal regulations that address the activities of this rule.

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

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. Also similar to Wisconsin, these states impose a fee for the screening and other services. However, it is not possible to accurately and specifically compare the proposed fee of \$109 to the fees set by these states because the disorders to be screened may differ, and the additional services and programs funded as permitted by statute and their level of needed funding may differ.

Illinois

Illinois's Department of Public Health assesses institutions or persons submitting a sample for newborn screening a fee of \$78, 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. Per an interview of an Illinois Newborn Screening Program representative, unlike Wisconsin, Illinois does not pay for low-protein food or special dietary supplements.

Iowa

Iowa's Department of Public Health assesses a fee of \$112 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). Per an interview of an Iowa Newborn Screening Program representative, unlike Wisconsin, Iowa does not pay for clinical services.

Michigan

Michigan's fee for screening newborns and other services is established under Michigan statute, 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 \$97.69. 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. Per an interview of a Michigan Newborn Screening Program representative, unlike Wisconsin, Michigan does not pay for low protein food.

Minnesota

Minnesota assesses its newborn screening fee in statute. Minn. Stat. s. 144.125 (1) requires its state commissioner of health to charge a fee of \$106 per specimen "so that the total of fees collected will approximate the costs of conducting the tests and implementing and maintaining a system to follow-up infants with heritable or congenital disorders, including hearing loss detected through early hearing detection and intervention program". Per an interview of a Minnesota Newborn Screening Program representative, unlike Wisconsin, Minnesota does not pay for special dietary treatment or diagnostic or clinical services. Minnesota pays for intensive review and follow-up for obtaining a blood test and initiating follow-up. Per an interview of a Minnesota Newborn Screening Program representative, unlike Wisconsin, Minnesota does not pay for special dietary treatment or diagnostic or clinical services. Minnesota pays for intensive review and follow-up for obtaining a blood test and initiating follow-up.

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