

Report From Agency

**ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH SERVICES
REPORT TO THE LEGISLATURE
CLEARINGHOUSE RULE 12-025
CH. DHS 115, SCREENING OF NEWBORNS FOR CONGENITAL AND
METABOLIC DISORDERS**

Basis and Purpose of Proposed Rule

Section 253.13 (1), Stats., requires attending physicians, certified nurse-midwives, and certified professional midwives to cause every infant born in Wisconsin to be screened for the congenital and metabolic disorders specified by the department by rule. Congenital and metabolic disorders screening, also known as newborn screening, are special tests for all newborns. Newborn screening helps parents find out if their baby has certain health problems. A newborn baby can look healthy, but have a serious disorder that cannot be seen. If not treated, these disorders can lead to slow growth, severe illness, brain damage, or possibly death. Early treatment can help prevent these serious problems.

Section 253.13 (2), Stats., as amended by 2011 Wis. Act 32, authorizes 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 the provision of 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. The department is required to credit the amounts received to appropriations accounts under s. 20.435 (1) (ja) and (jb), Stats. Section 253.13 (2), Stats., as amended by 2011 Wis. Act 32, also requires the department to impose the fee by rule. Previous to 2011 Wis. Act 32, the fee was imposed by WSLH by policy.

The department under the proposed order creates s. DHS 115.05 (3) to impose, by rule, a fee of \$109 for screening newborns for congenital and metabolic disorders and other services as directed under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32. The fee amount being imposed under the order is the same fee amount that is currently being imposed by the WSLH by policy to fund the same testing, services and programs that will be funded under the proposed rules. In effect, the proposed rules conforms the rule to statute.

Final Regulatory Flexibility Analysis

The \$109 fee in this proposed order will not have an impact on businesses, including small businesses, because the fee is unchanged since it was initially imposed by the WSLH in 2010. This proposed order only codifies the existing fee amount of \$109 in administrative rule. The rule does not include any requirements, including reporting requirements, schedules or

deadlines for compliance, performance standards, other measures or costs from which the department can exempt small businesses. It would be contrary to the objectives of s. 253.13 (2) Stats., to exempt small businesses from the fee required under s. 253.13 (2), Stats. First, s. 253.13 (1), Stats., requires attending physicians, certified nurse-midwives, and certified professional midwives to cause every infant born in Wisconsin to be screened for the congenital and metabolic disorders specified by the department by rule. Secondly, s. 253.13 (2), Stats., requires the department to impose a fee sufficient to pay for testing provided by the WSLH and include as part of the fee amounts to fund the provision of diagnostic and counseling services, special dietary treatment as prescribed by a physician, and periodic evaluation of infant screening programs, the costs of consulting with experts under s. 253.13 (5), Stats., the costs of administering the hearing screening program under s. 253.115, Stats., and the costs of administering the congenital disorder program operated under s. 253.13 (2), Stats. The \$109 fee amount is based on the costs to fund the provision of testing and services required under s. 253.13 (2), Stats.

The existing fee applies to hospitals, clinics and laboratories on behalf of hospitals, certified nurse-midwives, certified professional midwives, other birth attendants, other birth facilities, physicians, nurses, parents of newborns, insurers, the WSLH and the Newborn Screening Program.

Items submitted with Report to the Legislature

Section 227.19 (3), Stats., requires a copy of all of the following documents or information to be submitted with the agency’s report to the legislature. Below are the items included with this submissions with this report to the legislature.

Documents	Included in the Body of the Report	Attached to the Report	Not Received by DHS
Final proposed rule (text and summary)		√	
Rules Clearinghouse report		√	
Department response to Rules Clearinghouse report	√		
Fiscal Estimate/Economic Impact Analysis		√	
Revised Fiscal Estimate/Economic Impact Analysis			
Small Business Regulatory Review Board (SBRRB) suggestion, statement, report, or other material			√
Department response to SBRRB suggestion, statement, report, or other material			
Department of Administration report under s. 227.115 (2), Stats., on rules affecting housing			√

Department of Administration report under s. 227.137 (6), Stats., on rules with \$20 MM or more economic impact			√
Public Safety Commission (PSC) energy impact report, under s. 227.117 (2), Stats.			√
Department response to PSC energy impact report			

Responses to Legislative Council Rules Clearinghouse Recommendations

The department accepted the comment(s) made by the Legislative Council Rules Clearinghouse and modified the proposed rule as suggested.

Changes to the Analysis or Fiscal Estimate

Analysis

Changes were made to the rule’s analysis where suggested by the Legislative Council Rules Clearinghouse relating to clarity, grammar, punctuation and use of plain language and the following:

1. In paragraph one of the Plain Language Analysis, DHS changed “nurse-midwives” and “certified midwives” to “certified nurse-midwives” and “certified professional midwives” per public comment from Katherine Prown, the Legislative Chair of the Wisconsin Guild of Midwives.
2. In paragraph four of the Plain Language Analysis, DHS changed “nurse-midwives” and “certified midwives” to “certified nurse-midwives” and “certified professional midwives” per public comment from Katherine Prown, the Legislative Chair of the Wisconsin Guild of Midwives.

Fiscal Estimate/Economic Impact Analysis

No changes were made to the Fiscal Estimate/Economic Impact Analysis except where suggested by the Legislative Council Rules Clearinghouse relating to clarity, grammar, punctuation and use of plain language.

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Administrative Rules website on March, 23, 2012. A public hearing was held on May 25, 2012, in room 630 at 1 West Wilson, Madison, WI. Five persons attended the hearing. Public comments on the proposed rule were accepted until 4:30 p.m., on May 25, 2012.

List of Public Hearing Attendees and Commenters

The following is a complete list of the persons who attended the public hearing or submitted comments on the proposed rule, the position taken by the commenter and whether or not the individual provided written or oral comments.

	Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
1.	Judith Warmuth Wisconsin Hospital Association 5510 Research Park Drive Madison, WI 53725-9038	No position taken	Oral and Written
2.	Michele Smith 465 Henry Mall Madison, WI 53706	No position taken	Observed Only
3.	Maureen Kartheiser March of Dimes 5225 N. Ironwood Rd, Suite 200 Milwaukee, WI 53211	Support	Oral and Written
4.	Michael Farrell 19660 Warwick Dr Brookfield, WI 53045	Support in part; Oppose in part	Oral and Written
5.	Laura Farrell 19660 Warwick Dr Brookfield, WI 53045	No position taken	Observed Only
6.	Katherine Prown Legislative Chair, Wisconsin Guild of Midwives 414-550-8025	No position taken	Written
7.	James Meyer MD, FAAP American Academy of Pediatrics Wisconsin Chapter 563 Carter Court	No position taken	Written

	Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
	Suite B Kimberly, WI 54136		
8.	Christine Brown 1533 Kings Hill Drive Tomahawk, WI 54487	No position taken	Written
9.	Jill Paradowski RN, MS 3920 N. 88 th Street Milwaukee, WI 53222	No position taken	Written

Public Comments and Department Responses

The number(s) following each comment corresponds to the number assigned to the individual listed in the Public Hearing Attendees and Commenters section of this document.

Rule Provision	Public Comment	Department Response
General	The name of the credentials for midwives who are authorized to practice in Wisconsin are "certified nurse-midwife" and "certified professional midwife." The "certified midwife" credential is only recognized in three states. (6)	The department has changed the wording to "certified nurse-midwife" and "certified professional midwife" as suggested in the comment.
General	<p>Speaking as a pediatrician and father, I wish to voice my strong concern about the process for establishing fees for the newborn screening program. By following the “administrative rule-making” process for changing fees, Wisconsin infants are going to die because of inefficiencies of following a process that will take up to 18 months to change the fee. If the program could be more nimble in setting fees, then it could tailor its revenue for its commitments. The process needs to be streamlined.</p> <p>Additional test could/should be added to the screening but the spending authority is unclear. Without implementing these tests, infants end</p>	Section 253.13 (2), Stats., requires the department to impose the newborn screening fee by administrative rule. Under s. 253.13 (2), Stats., the department may no longer propose the fee by policy. Chapter 227, Stats., establishes the administrative rulemaking process.

Rule Provision	Public Comment	Department Response
	up costing Wisconsin businesses and taxpayers a lot of money. (4)	
General	As a retired public health nurse, I am concerned that the change to the rule ch. DHS 115 will delay important changes as they arise for our Wisconsin Newborn Screening Program. The program has been known for quality. In order for Wisconsin to continue to provide all of the test suggested by national newborn screening standards, there may be a need to increase the fee for testing and follow-up. This rule makes that process very cumbersome and lengthy, thereby extending the time that a new test would be added. Testing for 40 tests and follow-up for just over 100 dollars is such a small price to pay for the life of one infant. I am asking that this rule not go into effect and that the previous method of requesting increased funding for this program remain. (9)	Section 253.13 (2), Stats., requires the department to impose the newborn screening fee by administrative rule. Under s. 253.13 (2), Stats., the department may no longer propose the fee by policy. Chapter 227, Stats., establishes the administrative rulemaking process.
General	The Wisconsin Chapter of the American Academy of Pediatrics fully supports approval of the \$109 fee as a “permanent rule.” Children identified with abnormalities on Newborn Screening require specialized treatment. Failure to treat these conditions would result in	No response needed.

Rule Provision	Public Comment	Department Response
	<p>abnormalities in metabolism which would lead to brain damage and/or death. If a child is not adequately screened and interventions in treating metabolic disorders are not made early enough, the cost of prolonged and even permanent treatment would have a far-reaching financial impact on the state. Those who would be submitted to long-term custodial care as a result would affect their ability to become wage earners and taxpayers themselves, rather than being a burden on public and private resources. It is vital to the health of Wisconsin's newborns that a stable and reliable revenue stream be available to support the program, both in terms of testing costs and specialized formula costs. (7)</p>	
General	<p>As a mother of two children with PKU, I would like to offer my support for DHS 115, relating to a fee for screening newborns for congenital and metabolic disorders and other services. The newborn screening test literally saved their lives. Thanks to this test, my two boys are thriving. This is because they have access to the treatment needed to keep them healthy. I would like to thank the Department for continuing to support this critical</p>	No response needed.

Rule Provision	Public Comment	Department Response
	<p>program. If my children were to lose access to these services, I am not sure how my husband and I would afford their treatment. Our insurance company does not cover medical foods treatment for PKU, and the financial burden that would be placed on our family would be enormous. (8)</p>	
General	<p>The March of Dimes supports the need for these funds to run a state of the art Newborn Screening program. The March of Dimes counts on government, particularly the State of Wisconsin Department of Health Services, to fulfill their role in protecting and improving family health. The newborn screening system is designed to detect and treat these conditions as early as possible to prevent chronic illnesses, physical disability, mental retardation, developmental problems or even infant death. When test results are abnormal, early diagnosis and proper treatment can make the difference between lifelong impairment and healthy development. The March of Dimes respectfully asks you to support and maintain this fee to ensure that there are adequate funds for the program. With minimal</p>	No response needed.

Rule Provision	Public Comment	Department Response
	investment, these programs save money by helping to treat diseases before they cause a child permanent damage and disabilities. (3)	
General	The proposed fee is appropriate for the coming year, but it is difficult to predict expenditures for the program. There needs to be viable combination of predictability and agility for the newborn screening program. (4)	Section 253.13 (2), Stats., requires the department to impose the newborn screening card by administrative rule. Chapter 227, Stats., establishes the administrative rulemaking process.
DHS 115.05 (3)	The Wisconsin Hospital Association has pointed out the current process, as a sustainable business model, is broken. DHS has calculated that purchasers of the card will pay over \$7 million annually for the costs related to this program. Beyond purchasing the card, providers also must incur costs of staff time, tracking inventory, ordering, storing, mailing, and billing the cards. When DHS increased the fee in July 2010, the Medicaid program said that it would not pay for the increased fee. Other funding alternatives might be more sustainable. WHA appreciates that DHS established a task force to explore these issues. We ask that DHS propose a fee that is 10 percent below the current fee. (1)	After deliberation, the department has decided to keep the newborn screening card fee at \$109. The department in coordination with the Newborn Screening Program and Newborn Screening Advisory Group Umbrella Committee, of which the Wisconsin Hospital Association (WHA) is a member, will be referencing these comments as we move forward in cost-containment discussions. As the WHA mentioned in their comment, they had representation on the Newborn Screening (ad hoc) Task Force which is in process of providing final recommendations to the Umbrella Committee to 1) review factors affecting fiscal status of the NBS Program Develop recommendations to promote its financial sustainability; 2) review existing programmatic requirements and processes identified in state statute and administrative rule and develop recommendations to modify the process for adding and/or deleting tests from the NBS panel while considering ethical and cost/funding implications; and 3) review the process of fee setting .