

☛ **03hr_AC-CF_CRule_02-136_pt01**



(FORM UPDATED: 08/11/2010)

**WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS**

2003-04

(session year)

Assembly

(Assembly, Senate or Joint)

Committee on ... Children and Families (AC-CF)

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
(**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
(**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (May 2012)

Assembly

Record of Committee Proceedings

Committee on Children and Families

Clearinghouse Rule 02-136

Relating to screening of newborns' blood for congenital and metabolic disorders.
Department of Health and Family Services

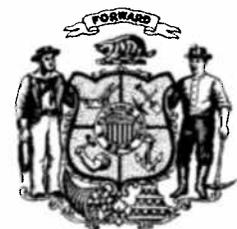
January 15, 2003 Referred to Committee on Children and Families.

February 15, 2003 No action taken.

David Matzen
Committee Clerk



WISCONSIN STATE LEGISLATURE





OFFICE OF LEGAL COUNSEL

1 WEST WILSON STREET
P.O. BOX 7850
MADISON WI 53707-7850

TELEPHONE: 608-266-8428
FAX: 608-267-1434
www.dhfs.state.wi.us

Scott McCallum
Governor

Phyllis J. Dubé
Secretary

State of Wisconsin

Department of Health and Family Services

January 3, 2002/3

The Honorable Allen J. Leseé, President
Wisconsin State Senate
17 West Main St., Room 401
Madison, WI 53702

The Honorable John Gard, Speaker
Wisconsin State Assembly
1 East Main, Suite 402
Madison, WI 53702

Re: Clearinghouse Rule 02-136
HFS 115, relating to screening of newborns' blood for congenital and metabolic disorders.

Gentlemen:

In accordance with the provisions of s. 227.19 (2), Stats., you are hereby notified that the above-mentioned rules are in final draft form. This notice and the report required by s. 227.19 (3), Stats., are submitted herewith in triplicate.

The rules were submitted to the Legislative Council for review under s. 227.15, Stats. A copy of the Council's report is also enclosed.

If you have any questions about the rules, please contact Susan Uttech at 267-3561.

Sincerely,

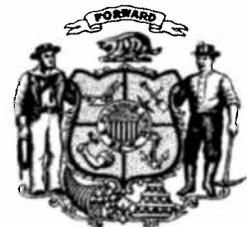
A handwritten signature in black ink, appearing to read 'Larry Hartzke', written in a cursive style.

Larry Hartzke
Administrative Rules Manager

cc Gary Poulson, Assistant Revisor of Statutes
Senator Joseph Leibham, JCRAR
Representative Glenn Grothman, JCRAR
Susan Uttech, Division of Public Health
Gary Radloff, Secretary's Office



WISCONSIN STATE LEGISLATURE



DATE: January 15, 2003

TO: Dave Matzen

Committee on Children and Families

FROM: Patrick E. Fuller, Assembly Chief Clerk

RE: Clearinghouse Rules Referral

The following Clearinghouse Rule has been referred to your committee.

CLEARINGHOUSE RULE 02-136

AN ORDER to create HFS 115.04 (9) to (13), relating to screening of newborns' blood for congenital and metabolic disorders.

Submitted by **Department of Health and Family Services.**

Report received from Agency on **January 6, 2003.**

To committee on **Children and Families.**

Referred on **Wednesday, January 15, 2003.**

Last day for action - **Friday, February 14, 2003.**

Under section 227.19 (4) of the Wisconsin Statutes, your committee has 30 days to take action or get an extension. The day **after** the official referral date is day one of your review period. Therefore, the 30th day should fall four weeks and two days after the referral date. For example, for Clearinghouse Rules referred on a Monday, a Wednesday would be your 30th day. For Clearinghouse Rules referred on a Tuesday, a Thursday would be your 30th day. For Clearinghouse Rules referred on a Wednesday, a Friday would be your 30th day. For Clearinghouse Rules referred on a Thursday or Friday, your 30th day would fall on a weekend. Therefore, your time would expire on the next working day (Monday) as provided for in s. 990.001 of the Wisconsin Statutes. Also, if the 30th day falls on a legal holiday, time would expire on the next working day.

Section 227.19 **requires** you to notify each member of your committee that you have received this Clearinghouse Rule. Although some committee chairs choose to do so, you are not required by law or rule to send a copy of the text of the rule to each member at this time. Instead, your notice could state that members should contact you if they wish to receive a hard copy of the rule. Another option would be to email the rule to members. **(Please note that the text of Rules beginning with the prefix "01" is available online in the Clearinghouse Rules infobase in FOLIO.)** Please put a copy of your official notification memo in the rule jacket.

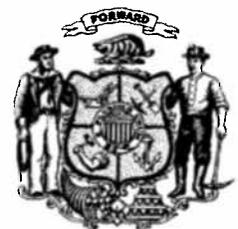
Three copies of the Clearinghouse Rule and its accompanying documents are contained in the jacket. If you wish to have your Legislative Council attorney review the Clearinghouse Rule, send him/her a copy. I only need one copy remaining in the jacket when you report it out of committee at the end of the review period.

The identical process is happening simultaneously in the Senate. Keep track of their action on the rule.

For assistance with the Clearinghouse Rule process, please consult Ken Stigler (6-2406) or your Legislative Council attorney. If you wish to learn more on this subject, read section 227.19 of the Wisconsin Statutes or part 2 of the *Administrative Rules Procedures Manual* written by the Revisor of Statutes Bureau and the Wisconsin Legislative Council staff.



WISCONSIN STATE LEGISLATURE





STATE REPRESENTATIVE

STEVE KESTELL

27TH ASSEMBLY DISTRICT

TO: Members of the Children and Families Committee

Representative Ladwig

Representative Albers

Representative Jeskewitz

Representative Vukmir

Representative Miller

Representative Sinicki

Representative Krug

FROM: Representative Steve Kestell, Chair

DATE: January 16, 2003

RE: Clearinghouse Rule 02-136

On January 15, 2003 the following clearinghouse rule submitted by the Department of Health and Family Services was referred to the Assembly Children and Families Committee:

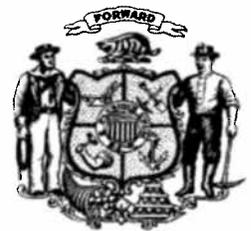
Clearinghouse Rule 02-136, an order to create chapter HFS 115.04 (9) to (13), relating to screening of newborns' blood for congenital and metabolic disorders.

The proposed rule relates to Wisconsin Statute 253.13, requiring that every infant born be subjected to blood tests for congenital and metabolic disorders. Parents, however, may refuse to have their infants screened for religious reasons. This rule change adds 5 amino acid-related disorders to the 8 disorders currently screened for under HSS. 115.04. The additional costs to screen for aminoacidopathies is less than \$1.00 per specimen. There is no anticipated increase in the surcharge during the proposed five-year pilot phase of adding the tests. The annual costs due to implementation of screening will total approximately \$29,000 and will be absorbed by the current lab and surcharge funds.

The deadline for committee action on this rule is **February 14, 2003**. If you are interested in obtaining a hard copy of the rule or requesting a hearing, please do so prior to the deadline date. This rule can also be accessed in FOLIO under the "Clearinghouse Rules" infobase.



WISCONSIN STATE LEGISLATURE





WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Richard Sweet
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Laura D. Rose
Legislative Council Deputy Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 02-136

AN ORDER to create HFS 115.04 (9) to (13), relating to screening of newborns' blood for congenital and metabolic disorders.

Submitted by **DEPARTMENT OF HEALTH AND FAMILY SERVICES**

11-11-2002 RECEIVED BY LEGISLATIVE COUNCIL.

11-25-2002 REPORT SENT TO AGENCY.

RNS:AS

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]
Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]
Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]
Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]
Comment Attached YES NO

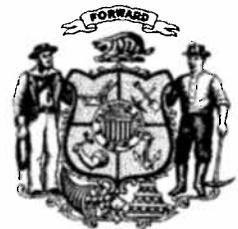
5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]
Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]
Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]
Comment Attached YES NO



WISCONSIN STATE LEGISLATURE



CRule
02-136

**PROPOSED ADMINISTRATIVE RULES – HFS 115
ANALYSIS FOR LEGISLATIVE STANDING COMMITTEES
PURSUANT TO S. 227.19 (3), STATS.**

Need for Rules

The early identification of particular congenital and metabolic disorders that are harmful or fatal to persons with the disorders is critical to mitigating the negative effects of such disorders. Therefore, Wisconsin Statute 253.13 requires that every infant born be subjected to blood tests for congenital and metabolic disorders, as specified in administrative rules promulgated by the Department. Parents, however, may refuse to have their infants screened for religious reasons. The Department has issued ch. HFS 115, Screening of Newborns for Congenital and Metabolic Disorders, to administer this statutory requirement. Currently, s. HFS 115.04 lists eight congenital and metabolic disorders for which the state hygiene laboratory must test newborn blood samples.

In determining whether to add or delete disorders from the list under s. HFS 115.04, s. HFS 115.06 directs the Department to seek the advice of persons who have expertise and experience with congenital and metabolic disorders. For this purpose, the Department established the Wisconsin Newborn Screening Umbrella Advisory Group. Section HFS 115.06 also lists six criteria on which the Department must base its decision to add to or delete disorders from s. HFS 115.04. These criteria are:

1. Characteristics of the specific disorder, including disease incidence, morbidity and mortality.
2. The availability of effective therapy and potential for successful treatment.
3. Characteristics of the test, including sensitivity, specificity, feasibility for mass screening and cost.
4. The availability of mechanisms for determining the effectiveness of test procedures.
5. Characteristics of the screening program, including the ability to collect and analyze specimens reliably and promptly, the ability to report test results quickly and accurately and the existence of adequate follow-up and management programs.
6. The expected benefits to children and society in relation to the risks and costs associated with testing for the specific condition.

In consideration of these criteria, the Wisconsin Newborn Screening Umbrella Advisory Group recently recommended that the Department add five aminoacidopathies, i.e., amino acid-related disorders, to the eight disorders currently screened for and listed in s. HFS 115.04. These disorders are:

- Maple Syrup Urine Disease;
- Homocystinuria;
- Tyrosinemia;
- Citrullinemia; and
- Argininosuccinic Acidemia.

Persons with these disorders can experience serious medical consequences such as failure-to-thrive, developmental delays, seizures, mental retardation and death.

The additional costs associated with these five additional screening tests is less than a dollar per baby screened because the amino acids in the blood sample are measured simultaneously with the acylcarnitines for Fatty Acid Oxidation and Organic Acidemias. In the absence of this screening, the Department estimates the annual Wisconsin costs for these

disorders to be \$144,909. The Department also estimates the annual Wisconsin costs of this screening to be \$29,134. Therefore, the cost benefit from these five screening tests is \$115,775.

The Advisory Group also recommended that the Department immediately begin screening newborns for these additional disorders. Before this testing can begin, the Department must change its rules to add the five new disorders to the existing list under s. HFS 115.04. Therefore, the Department issued identical emergency rules that became effective on October 12, 2002. These proposed permanent rules are intended to replace the emergency rules currently in effect.

Response to Clearinghouse Recommendations

The Clearinghouse did not have comments on the proposed rule.

Public Hearings Summary

The department held one public hearing on the proposed rule in Madison on December 17, 2002. The Department accepted comments until December 20, 2002.

One person, Elizabeth A. Schumacher of the Wisconsin Medical Society attended the hearing and submitted a letter of support. Another person, Carl S. L. Eisenberg, M.D., Fellow of the American Academy of Pediatrics, submitted a letter of support on behalf of the Wisconsin Chapter of the American Academy of Pediatrics.

Final Regulatory Analysis

The proposed permanent rule will not affect small businesses as "small business" is defined in s. 227.114 (1) (a), Stats.

PROPOSED ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
AMENDING RULES

To create HFS 115.04 (9) to (13), relating to screening of newborns' blood for congenital and metabolic disorders.

Analysis Prepared by the Department of Health and Family Services

The early identification of particular congenital and metabolic disorders that are harmful or fatal to persons with the disorders is critical to mitigating the negative effects of such disorders. Therefore, Wisconsin Statute 253.13 requires that every infant born be subjected to blood tests for congenital and metabolic disorders, as specified in administrative rules promulgated by the Department. Parents, however, may refuse to have their infants screened for religious reasons. The Department has issued ch. HFS 115, Screening of Newborns for Congenital and Metabolic Disorders, to administer this statutory requirement. Currently, s. HFS 115.04 lists eight congenital and metabolic disorders for which the state hygiene laboratory must test newborn blood samples.

In determining whether to add or delete disorders from the list under s. HFS 115.04, s. HFS 115.06 directs the Department to seek the advice of persons who have expertise and experience with congenital and metabolic disorders. For this purpose, the Department established the Wisconsin Newborn Screening Umbrella Advisory Group. Section HFS 115.06 also lists six criteria on which the Department must base its decision to add to or delete disorders from s. HFS 115.04. These criteria are:

1. Characteristics of the specific disorder, including disease incidence, morbidity and mortality.
2. The availability of effective therapy and potential for successful treatment.
3. Characteristics of the test, including sensitivity, specificity, feasibility for mass screening and cost.
4. The availability of mechanisms for determining the effectiveness of test procedures.
5. Characteristics of the screening program, including the ability to collect and analyze specimens reliably and promptly, the ability to report test results quickly and accurately and the existence of adequate follow-up and management programs.
6. The expected benefits to children and society in relation to the risks and costs associated with testing for the specific condition.

In consideration of these criteria, the Wisconsin Newborn Screening Umbrella Advisory Group recently recommended that the Department add five aminoacidopathies, i.e., amino acid-related disorders, to the eight disorders currently screened for and listed in s. HFS 115.04. These disorders are:

- Maple Syrup Urine Disease;
- Homocystinuria;
- Tyrosinemia;
- Citrullinemia; and
- Argininosuccinic Acidemia.

Persons with these disorders can experience serious medical consequences such as failure-to-thrive, developmental delays, seizures, mental retardation and death.

The additional costs associated with these five additional screening tests is less than a dollar per baby screened because the amino acids in the blood sample are measured

simultaneously with the acylcarnitines for Fatty Acid Oxidation and Organic Acidemias. In the absence of this screening, the Department estimates the annual Wisconsin costs for these disorders to be \$144,909. The Department also estimates the annual Wisconsin costs of this screening to be \$29,134. Therefore, the cost benefit from these five screening tests is \$115,775.

The Advisory Group also recommended that the Department immediately begin screening newborns for these additional disorders. Before this testing can begin, the Department must change its rules to add the five new disorders to the existing list under s. HFS 115.04. Therefore, the Department issued identical emergency rules that became effective on October 12, 2002. These proposed permanent rules are intended to replace the emergency rules currently in effect.

The Department's authority to create these rules is found in ss. 253.13 (1) and 227.11 (2) (a), Stats. The rules interpret s. 253.13 (1), Stats.

SECTION 1. HFS 115.04 (9) to (13) are created to read:

HFS 115.04 (9) Maple Syrup Urine Disease, ICD-9-CM 270.3.

(10) Homocystinuria, ICD-9-CM 270.4.

(11) Tyrosinemia, ICD-9-CM 270.2.

(12) Citrullinemia, ICD-9-CM 270.6.

(13) Argininosuccinic Acidemia, ICD-9-CM 270.6.

This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2) (intro.), Stats.

Wisconsin Department of Health
and Family Services

Dated:

By: _____
Phyllis Dubé
Secretary

SEAL: