

WISCONSIN LEGISLATIVE COUNCIL STAFF

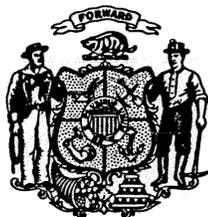
LCRC  
FORM 2

JUN 28 REC'D

**RULES CLEARINGHOUSE**

**Ronald Sklansky**  
Director  
(608) 266-1946

**Richard Sweet**  
Assistant Director  
(608) 266-2982



**David J. Stute, Director**  
Legislative Council Staff  
(608) 266-1304

One E. Main St., Ste. 401  
P.O. Box 2536  
Madison, WI 53701-2536  
FAX: (608) 266-3830

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**CLEARINGHOUSE REPORT TO AGENCY**

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[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 99-081**

AN ORDER to amend HFS 115.04 (intro.) and (1) to (7) and 115.06; and to create HFS 115.04 (8), relating to screening of newborns for congenital and metabolic disorders.

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

05-07-99 RECEIVED BY LEGISLATIVE COUNCIL.

06-03-99 REPORT SENT TO AGENCY.

RS:LR:jal

**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

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

To amend HFS 115.04 (intro.) and (1) to (7) and 115.06 and to create HFS 115.04 (8), relating to screening of newborns for congenital and metabolic disorders.

Analysis Prepared by the Department of Health and Family Services

The Department of Health and Family Services administers the Newborn Screening Program under s. 253.13, Stats. Under that program a sample of blood is drawn from nearly every newborn infant in the state before a child is discharged from the hospital, if the child was born in a hospital, or within one week of birth, if the child was born elsewhere, and tests are conducted by the State Laboratory of Hygiene on each blood sample to detect any of the congenital or metabolic disorders specified in ch. HFS 115, the Department's rules for the program. The conditions for which testing is done were specified by statute before November 1, 1992. Since then, s. 253.13 (1), Stats., has directed the Department to specify those conditions by rule.

The Department adds to or deletes from the rules conditions for testing of blood samples on the advice of the Newborn Screening Advisory Group made up of medical consultants, State Laboratory of Hygiene staff and other persons with expertise and experience in dealing with congenital and metabolic disorders, and in accordance with 6 criteria listed in s. HFS 115.06. The criteria include the availability of effective therapy for the condition and potential for successful treatment, the availability of mechanisms for determining the effectiveness of test procedures, and the expected benefits to children and society in relation to the risks and costs of the testing.

The Newborn Screening Advisory Group has unanimously supported the recommendation of Department staff to add at this time Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) and 13 other fatty oxidation and branched chain amino acid disorders as a new condition for which testing of blood samples drawn from newborns is conducted. It is estimated that through this testing 15 to 20 babies a year in Wisconsin will be identified as having one of the disorders. Morbidity and mortality are high for persons with the condition if treatment is not begun before the onset of clinical symptoms. Prompt initiation of treatment results in nearly 100% survival and normal development. Treatment is simple (diet supplementation and regulation) and inexpensive. The screening technology has only recently been developed.

This rulemaking order adds MCAD and the other 13 fatty acid oxidation and branched chain amino acid disorders as a new condition to the list of conditions in s. HFS 115.04 for which blood samples taken from newborns will be tested. The order also converts the lists found in ss. HFS 115.04 and 115.06 to a new form required by revised drafting standards.

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

SECTION 1. HFS 115.04 (intro.) and (1) to (7) are amended to read:

**HFS 115.04 Congenital and metabolic disorders.** Blood samples taken from newborns as required under s. 253.13 (1), Stats., shall be tested by the state laboratory for all of the following conditions:

- (1) Phenylketonuria (PKU), ICD-9-CM 270.1~~;~~
- (2) Galactosemia, ICD-9-CM 271.1~~;~~
- (3) Congenital hypothyroidism, ICD-9-CM 243~~;~~
- (4) Sickle cell disease and related hemoglobin abnormalities, ICD-9-CM 282.6~~;~~
- (5) Biotinidase deficiency, ICD-9-CM 266.9~~;~~
- (6) Congenital adrenal hyperplasia, ICD-9-CM 255.2~~;~~ ~~and~~
- (7) Cystic fibrosis, ICD-9-CM 277.0.

SECTION 2. HFS 115.04 (8) is created to read:

HFS 115.04 (8) Medium chain acyl-coenzyme A dehydrogenase deficiency (MCAD) and related disorders of lipid metabolism, ICD-9-CM 272.9.

SECTION 3. HFS 115.06 is amended to read:

**HFS 115.06 Criteria for adding or deleting conditions.** In determining which disorders are to be added or deleted from s. HFS 115.04, the department shall seek the advice and guidance of medical consultants, staff of the state laboratory and other persons who have expertise and experience in dealing with congenital and metabolic disorders. Criteria to be considered in adding or deleting disorders shall include all of the following:

- (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; and

(6) The expected benefits to children and society in relation to the risks and costs associated with testing for the specific condition.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health and  
Family Services

Dated:

By: \_\_\_\_\_  
Joseph Leean  
Secretary

SEAL:

SEP 15 1999



Tommy G. Thompson  
Governor

Joe Leean  
Secretary

State of Wisconsin

Department of Health and Family Services

OFFICE OF LEGAL COUNSEL

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

TELEPHONE: (608) 266-8428

September 15, 1999

The Honorable Fred Risser, President  
Wisconsin State Senate  
1 East Main, Suite 402  
Madison, WI 53702

The Honorable Scott Jensen, Speaker  
Wisconsin State Assembly  
1 East Main, Suite 402  
Madison, WI 53702

Re: Clearinghouse Rule 99-081

HFS 115, relating to screening of newborn children 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 Michael Pfrang at 266-7550.

Sincerely,

  
Paul E. Menge  
Administrative Rules Manager

cc Gary Poulson, Deputy Revisor of Statutes  
Senator Judy Robson, JCRAR  
Representative Glenn Grothman, JCRAR  
Michael Pfrang, Division of Public Health  
Kevin Lewis, Secretary's Office

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

Need for Rules

The Department of Health and Family Services administers the Newborn Screening Program under s. 253.13, Stats. Under that program a sample of blood is drawn from nearly every newborn infant in the state before a child is discharged from the hospital, if the child was born in a hospital, or within one week of birth, if the child was born elsewhere, and tests are conducted by the State Laboratory of Hygiene on each blood sample to detect any of the congenital or metabolic disorders specified in ch. HFS 115, the Department's rules for the program.

The Department adds to or deletes from the rules conditions for testing of blood samples on the advice of the Newborn Screening Advisory Group made up of medical consultants, State Laboratory of Hygiene staff and other persons with expertise and experience in dealing with congenital and metabolic disorders, and in accordance with 6 criteria listed in s. HFS 115.06. The criteria include the availability of effective therapy for the condition and potential for successful treatment, the availability of mechanisms for determining the effectiveness of test procedures and the expected benefits to children and society in relation to the risks and costs of the testing.

The Newborn Screening Advisory Group has unanimously supported the recommendation of Department staff to add at this time Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) and 13 other fatty oxidation and branched chain amino acid disorders as a new condition for which testing of blood samples drawn from newborns is conducted. It is estimated that through this testing 15 to 20 babies a year in Wisconsin will be identified as having one of the disorders. Morbidity and mortality are high for persons with the condition if treatment is not begun before the onset of clinical symptoms. Prompt initiation of treatment results in nearly 100% survival and normal development. Treatment is simple (diet supplementation and regulation) and inexpensive. The screening technology has only recently been developed.

This rulemaking order adds MCAD and the other 13 fatty acid oxidation and branched chain amino acid disorders as a new condition to the list of conditions in s. HFS 115.04 for which blood samples taken from newborns will be tested. The order also converts the lists found in ss. HFS 115.04 and 115.06 to a new form required by revised drafting standards.

Responses to Clearinghouse Recommendations

The Legislative Council's Rules Clearinghouse reviewed the proposed rules but did not have any comments on them.

### Public Review

A public hearing on the proposed rules was held in Madison on July 14, 1999. No one appeared at the hearing. The hearing record was kept open until July 21, 1999, for receipt of written comments. No written comments were received.

### Final Regulatory Flexibility Analysis

These rule changes will not affect small businesses as "small business" is defined in s. 227.114 (1) (a), Stats. The addition of another condition for which the same blood sample of a newborn child is screened will affect the State Laboratory of Hygiene, the Department for follow-up treatment, newborn children identified as having the particular condition who will benefit from the follow-up treatment, and their parents, and all parents of newborn children or their third-party payers for the additional cost (about \$5.50) of a delivery. No third-party payer is likely to be a small business, and in any case would likely absorb or else pass-on increased costs to parents.

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- (7) Cystic fibrosis, ICD-9-CM 277.0.

SECTION 2. HFS 115.04 (8) is created to read:

HFS 115.04 (8) Medium chain acyl-coenzyme A dehydrogenase deficiency (MCAD) and related disorders of lipid metabolism, ICD-9-CM 272.9.

SECTION 3. HFS 115.06 is amended to read:

**HFS 115.06 Criteria for adding or deleting conditions.** In determining which disorders are to be added or deleted from s. HFS 115.04, the department shall seek the advice and guidance of medical consultants, staff of the state laboratory and other persons who have expertise and experience in dealing with congenital and metabolic disorders. Criteria to be considered in adding or deleting disorders shall include all of the following:

- (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; ~~and~~ \_

(6) The expected benefits to children and society in relation to the risks and costs associated with testing for the specific condition.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health and  
Family Services

Dated:

By: \_\_\_\_\_  
Joseph Leean  
Secretary

SEAL: